VitaGuard® VG 2100

Apnea and Heart Rate Monitor

Operating instructions

getemed

Who should read which sections in these operating instructions?

The sections **3** to **7** colored blue at the top of the page and in the table of contents are intended specifically for caregivers without medical background knowledge.

The other sections are intended in particular for doctors and qualified medical staff.

1 General view and list of accessories

2 Intended use

3 Safety

4 Description

5 Steps before and after monitoring

6 Preparing for heart rate and apnea monitoring

7 Alarms, displays, and views during monitoring

8 Alarm and monitor settings

9 Information for the doctor and qualified medical staff

10 Algorithms and measuring principles

11 Evaluating stored data on a PC

12 Specifications

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NOTE Words and passages in SMALL CAPITALS in these operating instructions also appear on the display.

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1 General view and list of accessories

The general view shows the monitoring system's most important components.

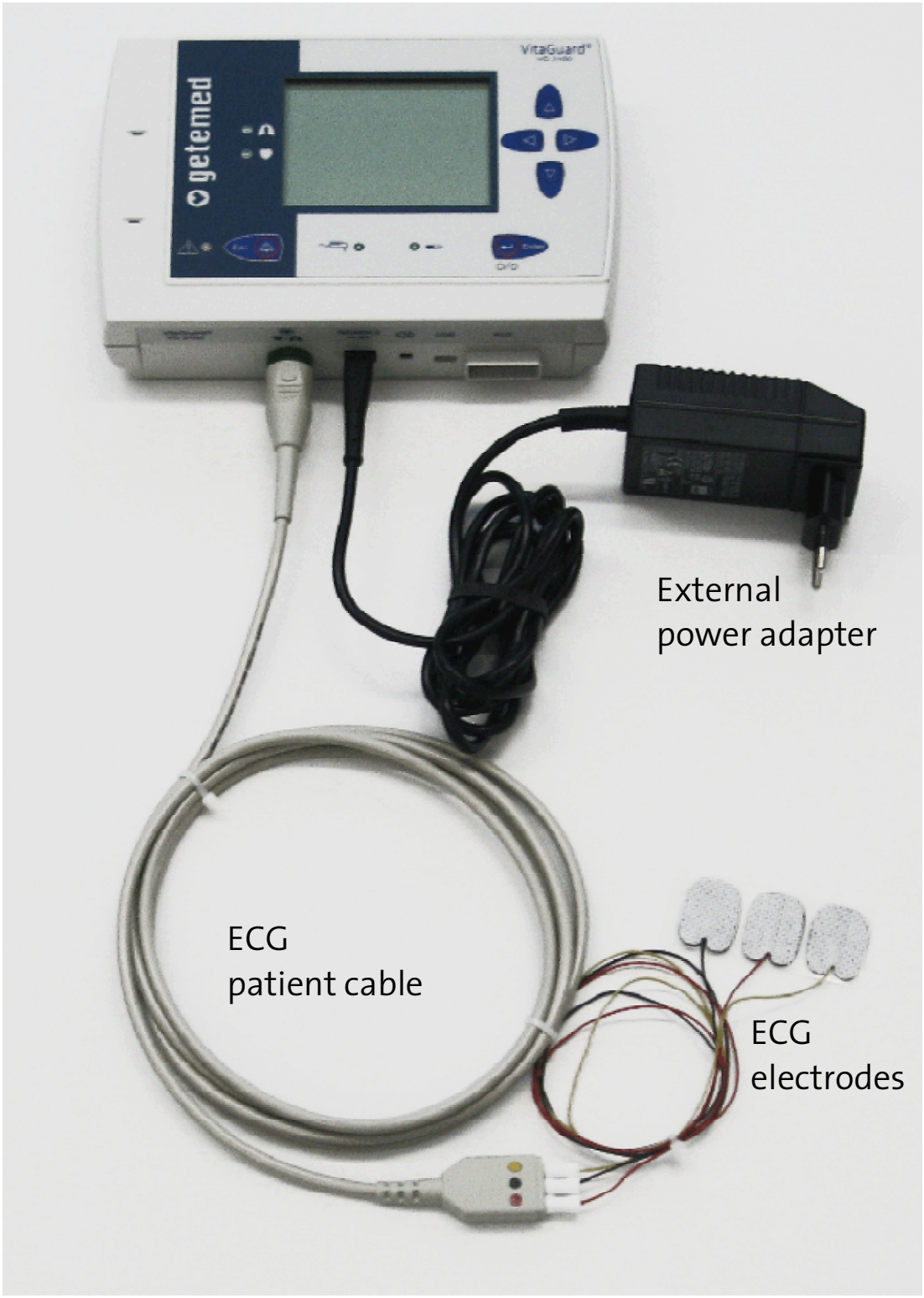


Fig. 1 General view of the monitoring system

The accessories listed in the following can be used together with VitaGuard® and can be ordered with the specified article numbers from getemed AG or authorized dealers. Please consult getemed AG or your authorized dealer for other approved accessories.

Product	**Article no. / REF**
VitaGuard® VG 2100 Monitor complete system 1 VitaGuard® VG 2100 monitor 1 ECG patient cable, 9 neonatal electrodes 1 NA3000-2 external power adapter 1 rechargeable block battery 1 device bag 1 operating instructions, 1 quick reference Transport case	7311 1022
NA 3000-2 external power adapter (110 V–240 V~ / 50–60 Hz)	7344 1101
NAK 3000-2 automobile power supply adapter	7344 1201
Rechargeable block battery	7344 2201
PK1-8P ECG patient cable	7341 1001
Kitty Cat™ neonatal electrodes (PU = 30 pcs)	70222
Operating instructions (English)	7381 1021
Alarm chart (English)	7383 1021
Device bag	7345 1001
VitaGuard® transport case (for the complete system)	7391 0001
AUX 01 RS232 cable for connecting VitaGuard® to a serial PC port	7341 2002
AUX-02 modem cable for connecting a modem to VitaGuard®	7341 3001

AUX-03 cable for connecting an external alarm unit to VitaGuard® 7341 5001

AUX-04 cable for connecting VitaGuard® to a nurse call system with 4 kV isolation 7341 5011

AUX-06 cable for connecting two external signal sources to VitaGuard® 7341 6001

2 Intended use

This section provides information on the intended use of VitaGuard® and the limitations of this intended use.

CAUTION Do not attempt to use VitaGuard® for detecting obstructive apneas. Obstructive apneas, i.e. respiratory arrest following an occluded respiratory tract, are not detected by VitaGuard®. Food debris or vomit, for example, can occlude the respiratory tract.

The doctor treating the patient is responsible for the application of VitaGuard®. The specific "Information for the doctor and qualified medical staff" can be found on page 79.

getemed AG recommends qualified training for the caregivers in potentially necessary resuscitation techniques. Clearing the respiratory tract and the resuscitation of babies and infants require particular know-how that the treating doctor should communicate to the caregivers.

2.1 Label on the back of the device

The device label serves as a unique identifier for VitaGuard®. In addition, the label bears important cautionary information.

On the device label you will find the manufacturer's name and address as well as the product and model name. The serial number of your device is given next to SN.

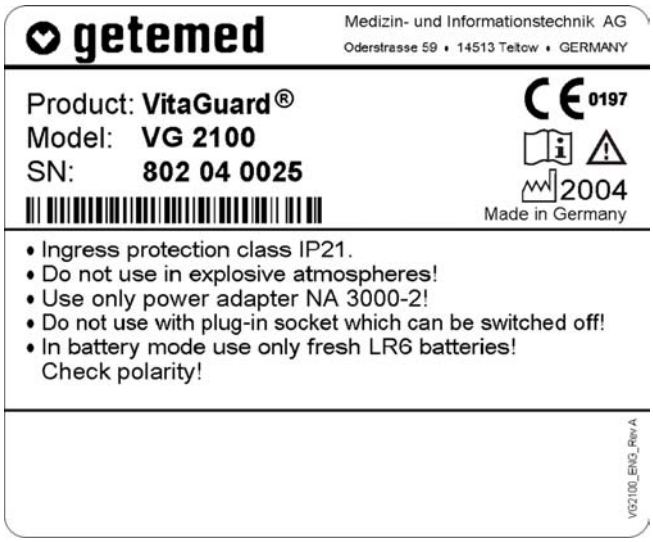

getemed
Medizin- und Informationstechnik AG
Oderstrasse 59 • 14513 Teltow • GERMANY
Product: VitaGuard®
Model: VG 2100
SN: 802 04 0025
CE 0197
2004
Made in Germany
• Ingress protection class IP21.
• Do not use in explosive atmospheres!
• Use only power adapter NA 3000-2!
• Do not use with plug-in socket which can be switched off!
• In battery mode use only fresh LR6 batteries!
Check polarity!
VG2100_ENG_Rev A

Fig. 2 Device label on the bottom of the device

2.2 Symbols and warnings

This symbol warns you that failure to observe these operating instructions can cause death or injury to the patient.

The book symbol means that you must not use the device when you are not familiar with the information contained in these operating instructions.

With this CE label and the CE approval number 0197 getemed AG confirms that VitaGuard® complies with all the pertinent regulations and in particular the requirements in Annex I of the Medical Devices Directive 93/42/EWG and that this has been approved by a notified body (TÜV Rheinland Product Safety).

This symbol means that the VitaGuard®'s ECG socket is a type CF (cardio floating) application part and that it is protected against the effects of defibrillation.

The factory symbol shows the year of manufacture.

Note the warnings on the device label.

Do not use in explosive atmospheres!

Use the NA 3000-2 power adapter only!

Warning: Do not connect to an electrical socket controlled by a wall switch!

Only new alkaline batteries (LR6 or AA) must be used when the device is powered by non-rechargeable batteries! Note the polarity!

2.3 Indications

VitaGuard® can be used to monitor patients with, for example, the following symptoms or treatment:

- unstable respiration
- life-threatening cardiac dysrhythmia
- conspicuous sleep laboratory findings
- facial and/ or cervical and thoracic dysmorphia
- distinct gastro-esophageal reflux
- ataxia

The heart rate and apnea monitor is suitable for adult, pediatric, and infant patients at home or in rooms used for medical purposes.

The apnea monitor is specifically intended for monitoring central apneas. Successful apnea monitoring requires a stable underground and a patient that lies quietly without moving.

2.4 VitaGuard® modes of operation

Depending on the risk group and the latest diagnosis, VitaGuard® allows the treating doctor to combine two monitoring parameters:

- heart rate monitoring
- apnea monitoring

The doctor can deactivate the apnea monitor in the RESPIRATION menu.

In addition to the fixed alarm limits for the heart rate monitor, the doctor or the qualified medical staff can also configure percentage deviations as alarm conditions.

The doctor or the qualified medical staff can find all other explanations they may need in the following sections:

- “Settings in the HEART RATE menu (SETTINGS PROTECTION OFF)” on page 98,
- “Settings in the RESPIRATION menu (SETTINGS PROTECTION OFF)” on page 103,

2.5 Intended use and performance

The intended use of VitaGuard® is to detect central apneas when the patient is completely immobile on a stable underground and to monitor the heart. VitaGuard® is designed for applications at home and in rooms used for medical purposes. VitaGuard® has no therapeutic effect.

VitaGuard® emits an acoustic and visual alarm when no respiration or movement is detected within a set period, when the measured heart rate values violate the set alarm limits for a period also set by the operator, and/or when no heartbeat has been detected for a set period. The alarm limits can be set within particular values specified by VitaGuard®.

Respiration and heart rate are monitored with adhesive ECG electrodes. VitaGuard® determines the heart rate from the ECG signal detected by the electrodes.

VitaGuard® features an impedance monitor that triggers a technical alarm when an electrode exhibits impedance values that are not compatible with proper operation. This is the case, for example, when an electrode has become detached.

Physiological data measured for a set period before and after an alarm are stored and can afterwards be evaluated and documented.

VitaGuard® can be operated with the NA3000-2 power adapter (9 V), the NAK3000-2 automobile power adapter (e.g. in the cigarette lighter), four non-rechargeable batteries, or a rechargeable block battery. Non-rechargeable batteries or the rechargeable block battery serve above all to safeguard the monitor’s functions during a power failure and to continue monitoring when patients are in transit.

2.6 Limitations on VitaGuard®'s intended use

Even when operated in accordance with its intended use, VitaGuard® cannot detect all life-threatening situations under certain unfavorable conditions.

2.6.1 Obstructive apneas are not detected

Obstructive apneas are not detected by VitaGuard®. The caregiver may have to remove food debris from the patient's oral cavity.

When an obstructive apnea at the same time triggers a bradycardia alarm (heart rate too low), resuscitation measures may need to be taken.

2.6.2 Limitations of the heart rate and central apnea monitor

VitaGuard® could misinterpret movements as respiration, e.g. in ambulances, cars, and prams or when a child is held in the arms. For this reason central apneas can be detected only when the patient is sleeping or is lying still, does not move, and is not being moved.

The heart rate can be monitored with electrodes also when the patient is moving, but sudden, vigorous movements can adversely affect the measuring accuracy.

A false heart rate is displayed during ventricular fibrillation or when the heart rate exceeds 270 beats per minute.

2.7 Information for the doctor on these operating instructions

In full knowledge of these operating instructions, the treating doctor must decide:

- whether the caregivers have to be trained in the performance of resuscitation measures,
- how the caregivers can be best prepared for monitoring and above all for the measures that must be taken in the event of an alarm,
- which VIEW should be displayed

Information on SETTINGS PROTECTION that sets the display modes and user configurations can be found on page 73.

“Information for the doctor and qualified medical staff” is found on page 79.

3 Safety

The responsible doctor decides whether the caregivers are able to use VitaGuard® for monitoring and whether they can implement appropriate measures in the event of an alarm.

3.1 Caregivers' tasks

With "caregivers" we mean those persons who are responsible during monitoring for the monitored patient's well-being, for example:

- parents or other members of the family,
- babysitters, when they too have been thoroughly prepared for the situation,
- nurses and other medically trained staff.

Observe in particular the information in those sections of the operating instructions that, like here, address you directly.

Observe the extensive safety instructions at the beginning of the section "Preparing for heart rate and apnea monitoring" on page 49.

VitaGuard® has no therapeutic effect. You may have to implement resuscitation measures in the event of an alarm.

The potential applications of VitaGuard® for high-risk patients are so many and diverse that we are unable to give any specific instructions on procedure in the event of an alarm. It is the doctor's task to inform high-risk patients and their caregivers in detail on the correct procedure in this case.

An alarm chart is available from getemed AG when monitoring children. This alarm chart presents a sequence of activities that are considered suitable by many medical specialists and pediatricians. Do not attempt to use VitaGuard® on more than one patient at a time.

Never modify settings without consulting the responsible doctor. Only the doctor knows the correct alarm limits and monitor configuration for each patient.

Never leave the patient's room without first making sure that the LEDs for heart and respiration are flashing.

Make absolutely sure that you can react to an alarm within a few seconds. Move away from patients only so far that you can reach them within ten seconds.

When you are not sure that VitaGuard® is in perfect operating order, check the patient's vital functions. Under no circumstances should you use VitaGuard® when you suspect a device defect.

In the event of ANY suspected VitaGuard® malfunction, continue to observe the patient until you can use a replacement monitor, or VitaGuard® has been examined by the doctor or authorized dealer.

Stop using VitaGuard® after the servicing interval of eighteen months has expired. Before the end of this period, make an appointment with your authorized dealer to check the safety and operability of your device.

Test the acoustic alarm unit every time you switch on VitaGuard®. This is explained in the section "Alarm test" on page 57.

CAUTION! When attaching the electrodes make sure that the plugs do not touch any other electrically conducting parts. Make sure that there can also be no contact with other electrically conducting parts when the electrodes become detached during monitoring.

Treat all leads and connections with particular care, and never use the connecting cables to lift VitaGuard®.

Switch off VitaGuard® before boarding an aircraft. When you want to transport VitaGuard® in your luggage, you should remove the batteries. This prevents other pieces of luggage from switching on the device by accident. An activated, but disconnected VitaGuard® will generate acoustic alarm signals.

3.2 Allergy risks to patients

Attach ECG electrodes to intact areas of skin only.

So that the permanent contact with the electrodes does not put too much of a strain on the patient's skin, the electrodes can be placed in the vicinity of the optimal site.

All materials that are used with VitaGuard® and can come into contact with patient or caregivers during normal operations are free of latex and are non-toxic in accordance with the standard ISO 10993-1.

getemed AG recommends replacing the adhesive electrodes used to monitor heart rate and apnea as soon as they start to lose their adherence. The special gel for the electrodes has been developed to avoid skin irritation, even after several months' monitoring on newborns.

Nevertheless, patients with sensitive skin may suffer allergic reactions in the form of reddened skin and blistering that in serious cases may look like burns. When the skin exhibits such changes, you must immediately inform the doctor. A change of electrode type may help.

3.3 Possible external interference to monitoring

Please bear in mind the possibility of other risks that are not listed here that can be caused by your specific monitoring environment.

3.3.1 Installation and environment

We recommend hanging VitaGuard® in the delivered bag at a place where the display can be easily viewed.

Check, as described in the section "Alarm test" on page 57, that you can hear alarms and where you can hear them. Think also of the activities that cause noises, for example showering or vacuuming. Think before you raise the volume of your television or stereo. Also,

the VitaGuard®'s alarm outlet should not be obstructed by any objects that absorb sound.

Never place VitaGuard® or the power adapter such that they could fall on the patient. For example, the power adapter could become detached from an overhead socket when the cable is pulled.

Do not immerse either VitaGuard® or the accessories in liquids.

Variations in temperature and air humidity could lead to condensation forming in and on VitaGuard®. Wait for at least two hours after VitaGuard® has visibly dried on the outside before using it for monitoring.

Do not operate VitaGuard® in environments containing explosive gases, flammable substances, nitrous gases, or highly oxygen-enriched atmospheres. Do not use VitaGuard® at extreme temperatures below 5 °C or above 40 °C. Do not place VitaGuard® near heat sources such as radiators, ovens, etc. Do not expose it to direct sunlight.

Always lay all cables and in particular any extension cables so that nobody can trip over them.

Do not place VitaGuard® directly next to the patient's head: risk of hearing damage!

3.3.2 Noise risks to monitoring

When the alarm cannot be set to a volume that is sufficiently above the prevailing ambient noise levels, you must keep VitaGuard® and its display within view. The visual signals from the alarm LED and display must then be relied upon to recognize critical situations.

You can also use the external alarm unit available from getemed AG that raises the volume of the alarm signals from VitaGuard®.

Information on the alarm signal types and volumes can be found in "Alarms, displays, and views during monitoring" on page 57. The alarm pitch is set as explained in the section "SYSTEM menu – general settings" on page 72.

3.3.3 Electrostatic interference

Electrostatic build-up that, for example, a person can pick up on certain carpets must not discharge through the VitaGuard® connector sockets or the electrodes' electrically conducting parts.

For this reason, avoid touching the electrically conducting parts, or discharge any electrostatic build-up beforehand by, for example, touching an earthed water pipe or heater.

3.3.4 Electromagnetic interference

VitaGuard® is not designed for applications near strong electromagnetic fields. These interference fields are frequently emitted by devices with large electric power consumptions. Keep a good distance from e.g. washing machines, computers, microwaves, vacuum cleaners, power tools, etc.

The device and the system can be used in the home and in all other environments that public utilities supply directly.

Bear in mind that portable and mobile HF communication devices, e.g. cellular phones, radio equipment, walkie-talkies, etc., can interfere with the monitor and influence its operability.

Bear in mind that non-approved accessories can amplify emitted interference and reduce the device's immunity.
Do not place the monitor directly next to other electrical equipment, and do not stack monitors on top of each other.

When the monitor has to be placed next to or on other equipment, check that the monitor operates as designed in this environment.
We recommend you to check at regular intervals:
– that the displayed signals are not disrupted when the patient is not moving,
– whether the same technical alarm messages are repeatedly displayed.

When you discover disruptions:
– if possible, switch off the interfering equipment or move this equipment to another site.

VitaGuard® uses high-frequency signals exclusively for its internal functions. As a result, its emitted interference is very low, and disruption to neighboring electronic equipment is unlikely.

False diagnoses are possible when monitored values are corrupted by interference from electric or electromagnetic fields and this escapes the doctor's attention. Every time you analyze stored data, consider the possibility of interference from electric or electromagnetic fields.

VitaGuard®'s emitted interference and immunity to external interference are within the limits for life-supporting systems stipulated in the standard EN 60601-1-2.

3.4 Safety with approved accessories only

Use VitaGuard® only with the delivered or approved accessories and in accordance with the information contained in these and the accessories' operating instructions.

Electrodes, cables, and power adapters can be ordered from your authorized dealer or directly from getemed AG. The telephone number of your authorized dealer was given to you during your training on how to operate the device, or it is found on a label your authorized dealer has attached to VitaGuard®.

Bear in mind that monitoring can continue without interruption only as long as the required consumables are available. In emergencies of this nature you can call your authorized dealer, who provides 24-hour emergency services. Please try, however, to avoid unnecessary stress for both yourself and your authorized dealer, and order your consumables in good time.

The modem used to transfer monitoring data must comply with the requirements under the German and European standard DIN EN 60950 “Safety of IT Equipment” with the amendments A1–A4. These details are found in the modem’s operating instructions.

3.5 Handling patient cables

Always lay patient cables at a good distance from the patient’s head and neck. Lay each patient cable inside the clothing, and secure it in place in such a way that no harm can come to the patient or cable (strangulation, twisting).

Make sure when laying and securing patient cables that these cannot kink (kinking causes damage).

For hygiene reasons, always use the same patient cable on the one patient. Disinfect patient cables before using them on a new patient.

When more than one monitor is used in the one environment, each monitor should always be connected to the same patient cables and the same power adapter. Faults can therefore be located and remedied faster.

3.6 Power supply reliability

Before first using VitaGuard® for monitoring, familiarize yourself with the section “Power supply” on page 34. Monitoring is safeguarded only when the power supply is in perfect operating order.

CAUTION: Danger of electric shock! Never open the external power adapter or the connecting cable.

Exclusively the NA 3000-2 approved for VitaGuard® must be used as the external power adapter.

VitaGuard® is usually delivered with the external power adapter for European supply networks. For other supply networks, use only the plug adapters available from getemed AG.

Do not use the external power adapter in sockets that can be switched off or dimmed.

When the VitaGuard® external power adapter is plugged into a multiple socket outlet, only the modem may be connected to this outlet simultaneously.

When an extension cable is used with a multiple socket outlet, this outlet must not lie on the floor. Otherwise water may penetrate the outlet and damage the monitor.

The external power adapter and the power outlet must be free of damage.

Never use the external power adapter's cable to lift VitaGuard®.

Stop using the external power adapter when it has fallen or been dropped.

Do not operate the external power adapter in a damp environment (e.g. in the bathroom).

Always leave the batteries in VitaGuard®, even when this is operated through the external power adapter.

VitaGuard® operates with batteries: either non-rechargeable batteries or a rechargeable block battery. VitaGuard® must be operated only with the rechargeable block battery available from getemed AG or new alkaline non-rechargeable 1.5 V batteries (LR6 or AA), e.g. VARTA UNIVERSAL ALKALINE. Bear in mind that cheaper non-alkaline non-rechargeable batteries can have a considerably reduced operating lifetime, in some cases only 10–15% of the brand name batteries we recommend.

Do not under any circumstances use single rechargeable batteries available on the market.

Never use a non-rechargeable battery and a rechargeable battery together in the device, and never mix old and new batteries.

To prevent leaking batteries from damaging health and property, remove non-rechargeable batteries from VitaGuard® when it is not used for longer than a week. Information on “Replacing batteries” can be found on page 36.

3.6.1 Battery voltage indicator

When VitaGuard® is powered only by non-rechargeable batteries, check the battery voltage indicator on the display every hour. At least one quarter of the battery symbol must be black.

Fig. 3 Battery voltage indicator

When VitaGuard® is powered from the supply network and commercially available non-rechargeable batteries are inserted, check the battery voltage indicator on the display every day. Even when the device is powered from the supply network, you must replace the non-rechargeable batteries as soon as one quarter of the battery symbol on the display is black.

If necessary, a display message will prompt you to insert new non-rechargeable batteries or to recharge the block battery.

3.6.2 Interruptions to the power supply

When the external power adapter is connected VitaGuard® operates automatically in supply network mode. When the supply network fails, VitaGuard® switches automatically to battery mode – when batteries are inserted.

As long as VitaGuard® is powered from the external power adapter or the automobile power supply, the green LED next to the power adapter symbol lights up.

Normal voltage fluctuations in the supply network do not adversely affect monitoring with VitaGuard®. Following a power supply failure,

the current alarm settings are retained for at least thirty days and are again available when the device is switched back on.

3.6.3 Using the rechargeable block battery

Note the warnings on the rechargeable block battery's label.

Do not open or short-circuit!

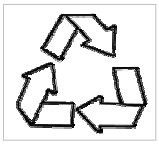
Do not throw into a fire!

Avoid temperatures over 50 °C!

The charging time for the block battery is at most six hours.

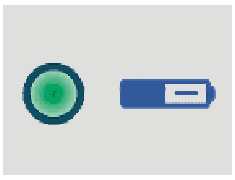
Fig. 4 Rechargeable block battery

Also note the recycling symbol on the label. This means that the block battery must be recycled when its service life has expired.



Do not expose the block battery to direct sunlight. For example, temperatures greater than 50 °C can easily occur on a vehicle's dashboard or rear shelf.

When you intend to use VitaGuard® powered from the rechargeable battery block and disconnected from the supply network, you must first make sure that the block battery is fully charged. For this reason, check the "Battery charging" LED. The battery is being charged as long as this LED light is continuously on. When the LED flashes every second, the battery is full and compensation charging is activated.



Sometimes the LED will go out for a short time in the interval between battery and compensation charging.

3.7 Safety with proper maintenance only

VitaGuard® can operate safely and reliably over the long term only when it is subject to proper maintenance and use.

Check visually for any damage on VitaGuard®, the patient cables including the connections, the external power adapter, and the electrodes every time you use VitaGuard® for monitoring.

Every eighteen months at the latest VitaGuard® and accessories must be serviced by getemed AG to comply with safety regulations.

Repairs must be performed by getemed AG only. Clarify the necessary procedure with your authorized dealer.

For the protection of our service personnel, disinfect VitaGuard® and the patient cables with Virkon®, available as a spray or wiping solution, before sending them to getemed AG.

3.7.1 Cleaning VitaGuard® and accessories

Before cleaning VitaGuard®, remove the batteries.

Before cleaning VitaGuard®, detach the electrodes and cables from the monitor and from the patient.

Do not under any circumstances use solvents like ether, acetone, or benzene. These substances can cause malfunctions and attack the housing plastic.

Also, do not use any cleaning agents containing abrasive substances and no coarse brushes or hard objects.

VitaGuard® and accessories can be cleaned any number of times when the recommended cleaning agents are used.

VitaGuard® and accessories must not be sterilized.

VitaGuard® and the cable plugs must not be immersed or otherwise penetrated by liquid.

Cleaning the exterior is best done with a non-linting cloth moistened slightly with water or a mild soap solution.

getemed AG recommends disinfecting the device with Virkon®, available as a spray or wiping solution.

Patient cables can be cleaned with liquid Cable Care or with a 70% alcohol solution. Baby oil has proved to be effective in removing residue from adhesive strips.

The VitaGuard® bag can be washed by hand at 30 C. It must not be put in the laundry dryer.

3.7.2 Checking and cleaning the battery terminals

Check the battery compartment every month for traces of leaking and for deposits on the battery terminals indicating leaks. Contact your authorized dealer and clarify further procedures when a battery starts to leak.

The battery compartment and how to replace the batteries are explained in the section “Replacing batteries” on page 36.

3.8 Disposing of non-rechargeable batteries, the device, and accessories

getemed AG takes back all of the parts it delivers. For hygiene reasons these parts do not extend to consumables like electrodes that have been in direct contact with the patient.

The symbol of the crossed-out waste container on the battery packaging is to remind you that under no circumstances must you dispose of batteries in normal household waste. As the end consumer you are legally obliged to return used batteries or dispose of them properly. You can return used batteries to us.

Place consumables like electrodes in a plastic bag before disposing of them in household waste.

Please do NOT send us ANY used electrodes.

Like every electronic device, VitaGuard® and accessories contain metal and plastic parts that must be disposed of in such a way that they do not pollute the environment after their service live. For this reason, the device and accessories may be sent to getemed AG in an adequately stamped package, when possible in the original packaging, for free and proper disposal.

4 Description

We recommend placing VitaGuard® in the bag provided. This bag protects the monitor and can be hung from a site where it cannot fall.

Fig. 5 VitaGuard® and bag with power and patient cables

4.1 Power supply

VitaGuard® is usually delivered with the power adapter for European supply networks. For other supply networks, contact getemed for the appropriate plug adapter. Observe the information in “Power supply reliability” on page 26.

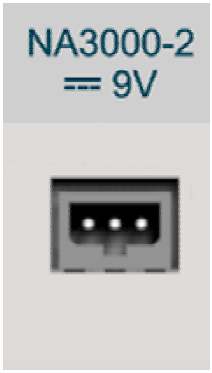


Fig. 6 Power adapter socket

VitaGuard® is normally supplied by the power adapter (Fig. 7, left) in the 230 V/ 50 Hz supply network.

The NAK 3000-2 automobile power supply adapter (Fig. 7, right) for vehicle dashboards can be inserted in this socket.

Fig. 7 Power adapter for 230 V/ 50 Hz supply network and automobile power supply

When VitaGuard® is supplied by the external power adapter, the green LED lights up next to the power adapter symbol. In addition, the display backlight is activated when VitaGuard® is switched on.

When VitaGuard® is supplied by the power adapter only, without inserted batteries, a display message will prompt you to insert batteries.

When VitaGuard® is supplied by the power adapter, charging of the inserted rechargeable block battery is activated. The LED next to the battery symbol illuminates.

4.1.1 Power failure with inserted batteries

VitaGuard® automatically switches to battery mode when the external power supply fails or the power adapter is disconnected. In this event a technical alarm is permanently emitted until the power supply has been reinstated or the <Esc> key pressed.

When the supply network LED is off, but you can still see the usual monitor displays, VitaGuard® is being supplied by the batteries.

4.1.2 Power failure without batteries

VitaGuard® is fitted with an internal battery. This provides the voltage for an acoustic signal that is emitted when monitoring cannot be continued during a power failure.

The acoustic alarm from the internal battery does not stop until VitaGuard® has been switched back on after the power adapter has been reconnected or batteries have been inserted.

A power failure jeopardizes monitoring when

- the batteries in the VitaGuard® are nearly depleted or
- no batteries have been inserted and VitaGuard® is disconnected from the external power adapter.

To stop the power draw on the internal battery, it is important that non-rechargeable batteries are inserted as quickly as possible or, better, the power adapter is reconnected.

VitaGuard® must not be used for monitoring when the internal battery is depleted. This status appears on the display.

A new internal battery can be installed at getemed AG only, so you must continue monitoring with a replacement device until the internal battery has been displaced.

4.1.3 Replacing batteries

Switch off VitaGuard® before replacing batteries.

Push back the catch and lift off the battery cover to open the battery compartment. Insert either four non-rechargeable batteries or the rechargeable block battery.

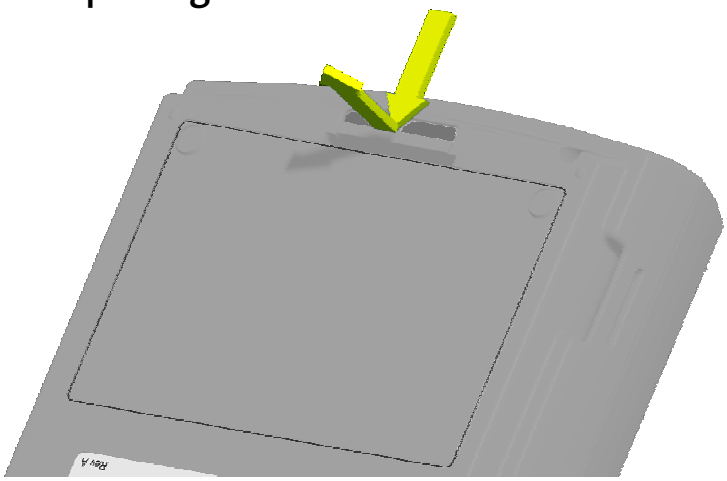


Fig. 8 Opening the battery compartment

Make sure that the + symbols on the batteries and in the compartment match before inserting non-rechargeable batteries.

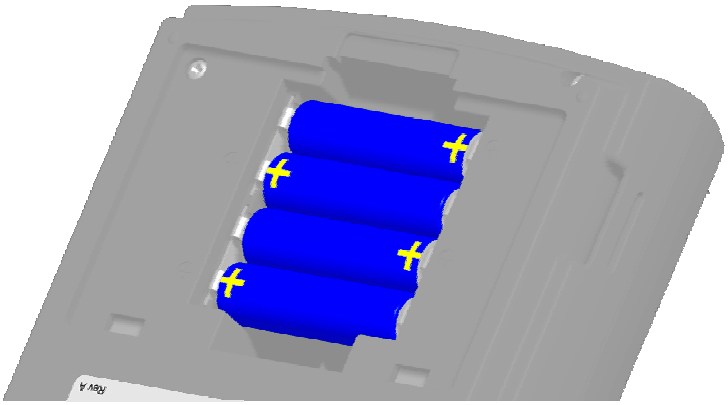


Fig. 9 Opened battery compartment and polarity

Observe the following instructions when you use the rechargeable block battery.

- Never use force to insert the block battery.
- The bottom of the block battery has a guide groove that prevents the battery from being inserted the wrong way. Make sure when inserting the block battery that the labeled side is on the top and the metal terminals point to the device label.

- You will feel a slight pressure from the terminal spring connections when inserting the block battery.

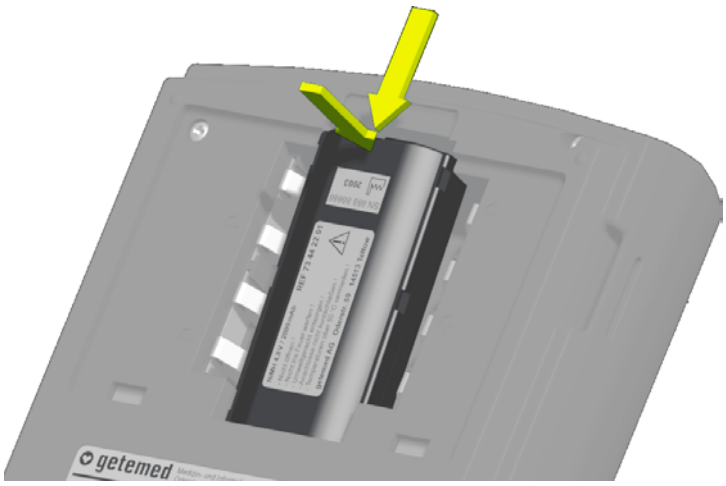


Fig. 10 The arrows show how the block battery is correctly inserted.

4.1.4 Using the automobile power supply adapter

Use only the NAK 3000-2 automobile power supply adapter to operate VitaGuard® from a vehicle's dashboard.

Do not leave the automobile power supply adapter overnight in the vehicle (particularly during the cold season). Otherwise condensation may form on and in the device.

The NAK 3000-2 automobile power supply adapter is connected to the VitaGuard® power adapter socket. NAK 3000-2 features a universal safety plug (DIN ISO 4165) for the dashboard lighter. Automobile power supply mode is indicated on VitaGuard® by the green LED beside the power adapter symbol.

The specifications of the automobile power supply adapter are as follows:

Input	Automobile voltage supply at 12–24 V
Output	9 Vdc
Max current	< 500 mA
Operating temperature	+5 to +50 °C
Connection to VitaGuard®	3-pin plug
Connection to automobile supply	Universal safety plug (DIN ISO 4165)
Connecting cable length	2 m ± 20 cm

4.2 VitaGuard® connections

Fig. 11 Overview of VitaGuard® connections

For safety reasons, only those accessories that getemed AG has delivered or approved must be connected to VitaGuard®.

Hold VitaGuard® firmly with one hand when connecting and disconnecting plugs.

Never use force when connecting and disconnecting cables. Always insert and remove the plugs parallel to the sockets to prevent damage to the sensitive contacts.

Only the doctor, in full knowledge of the information under “Connections to the USB and AUX ports” on page 81, must decide which devices are connected to the USB and AUX ports.

4.2.1 Patient cable for electrodes

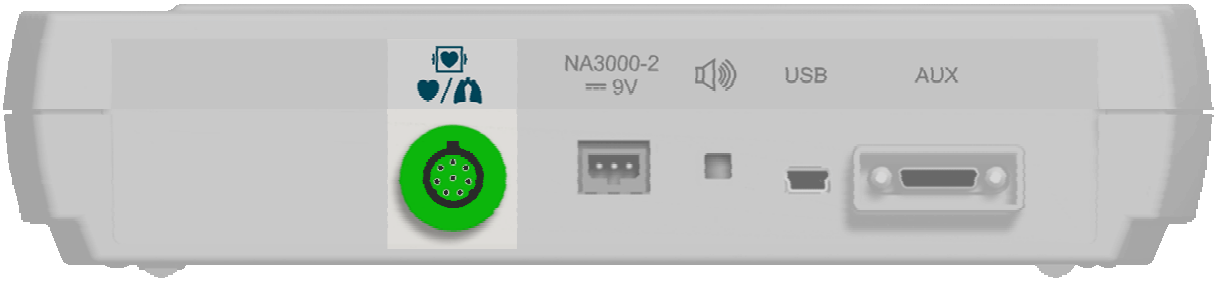


Fig. 12 Electrode socket

The patient cable for the electrodes for heart rate and apnea monitoring is connected to this socket.

4.2.2 Power adapter

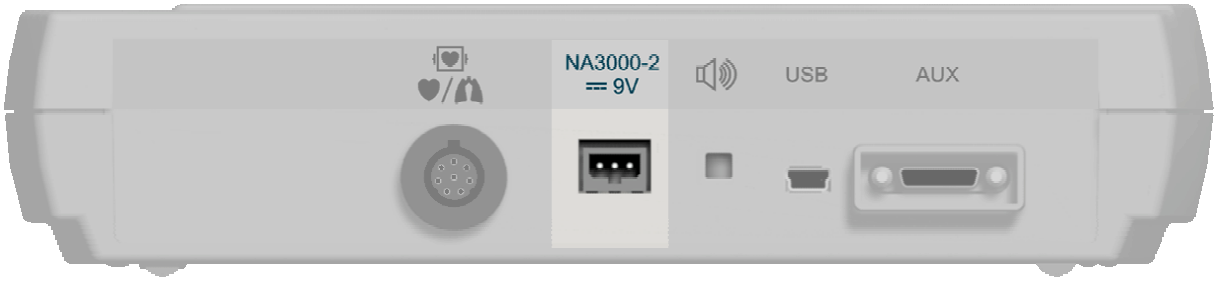


Fig. 13 Power adapter socket

The external power adapter socket is for connecting the NA 3000-2 external power adapter or the NAK 3000-2 automobile power supply adapter.

4.2.3 Sound outlet (no socket)

Fig. 14 Sound aperture

The outlet in the figure is not a socket, but a sound hole for the internal system monitor buzzer.

This outlet emits a pulsating sound when the external power adapter is disconnected from the monitor and no batteries are inserted.

The sound outlet is located between the cable sockets so that it cannot be covered by objects such as cushions or curtains.

4.2.4 USB port

Fig. 15 USB port

The USB (universal serial bus) port serves to read out stored data and to modify the VitaGuard® settings via a PC.

4.2.5 AUX port

Fig. 16 AUX port

The AUX (auxiliary) port can take the following connections:

- Two analog inputs
- Modem for communicating data
- Nurse call unit
- External alarm unit

VitaGuard® cannot confirm whether an alarm signal has been reported by a nurse call unit. As explained in the section “Alarm test” on page 57, check each time you switch on the device that an alarm signal is really transferred and the alarm reported.

Measure the time it takes for an alarm to be reported and the time needed to reach the patient. No more than ten seconds must pass between these times. Observe the operating instructions for the nurse call unit.

4.3 Membrane key panel

Do not apply excess pressure to the keys.

VitaGuard® recognizes key presses only when the keys have been pressed for about one second.

There are six membrane keys on the top side of VitaGuard®.

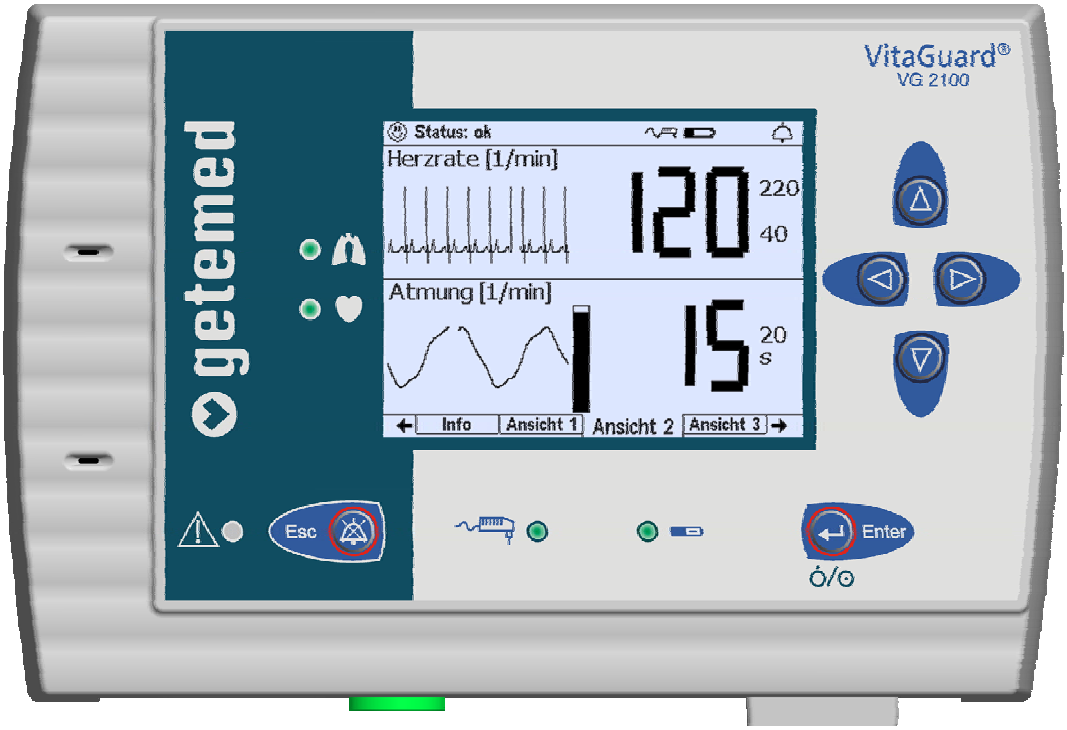


Fig. 17 Keys on the top side

4.3.1 Direction keys

With the direction keys you navigate from one window to the next.

The direction keys also allow you to navigate within the menu structure.

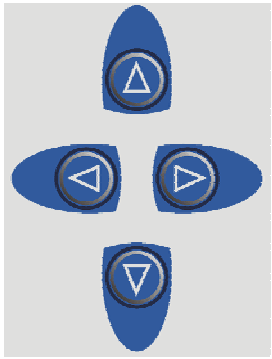


Fig. 18 Direction keys

4.3.2 <Enter> key

- The <Enter> key switches VitaGuard® on and off.
- The <Enter> key also lets you confirm changes to the monitor settings.

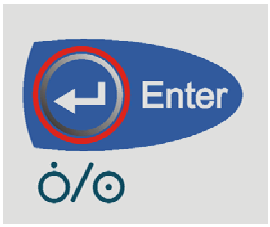


Fig. 19 <Enter> key

4.3.3 <Esc> key

- When an alarm is triggered, the <Esc> key serves to deactivate the acoustic alarm signal for a set alarm mute time. During an alarm condition the red alarm LED and the violated alarm limit flash. The acoustic alarm is again emitted if the alarm condition persists after the alarm mute time has expired. Pressing the <Esc> key during the alarm mute time a second time reactivates the acoustic alarm.

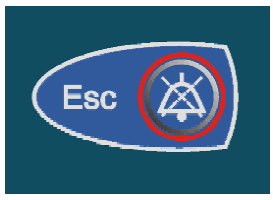


Fig. 20 <Esc> key

- Also when an alarm has automatically ended (because the vital functions have restabilized by themselves) the alarm LED and the violated alarm limit continue to flash until you press the <Esc> key. The alarm LED, however, flashes slower than during an alarm.

- The <Esc> key cancels unsaved changes to the monitor settings or moves back to the next-higher menu.

4.4 Color LEDs (Light Emitting Diodes)

When VitaGuard® is switched on, all LEDs light up for a short time so that you can see they work properly. During this time, the alarm LED first lights up red and then yellow.

4.4.1 Alarm LED

- In the event of a higher-priority alarm, i.e. a physiological alarm, the alarm LED flashes red.
- In the event of a medium-priority alarm, i.e. a technical alarm, the alarm LED flashes yellow.

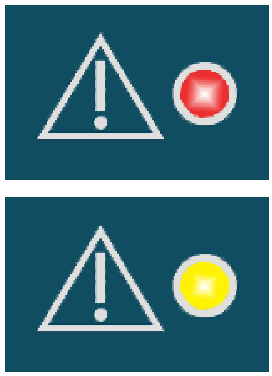


Fig. 21 Alarm LED

4.4.2 Heart and respiration LEDs

The LED with the heart symbol flashes with every heartbeat of the patient. In other words, this LED flashes as fast as the heart beats.

The LED with the lungs symbol lights up with every detected breath of the patient when the patient does not move and is not moved. In other words, this LED flashes as fast as the patient breathes.

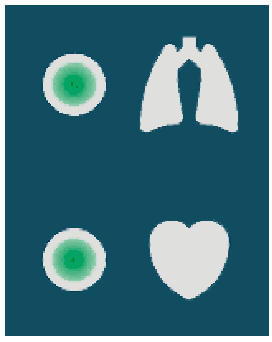


Fig. 22 Heart and respiration LEDs

These two flashing green LEDs show you even in complete darkness that monitoring is activated.

Also, the SYSTEM menu lets you switch on and off an acoustic signal that is emitted synchronously with the heartbeat or respiration.

4.4.3 Power supply and battery LEDs

- When the LED with the power adapter symbol lights up, VitaGuard® is being powered from the supply network or an automobile power supply.

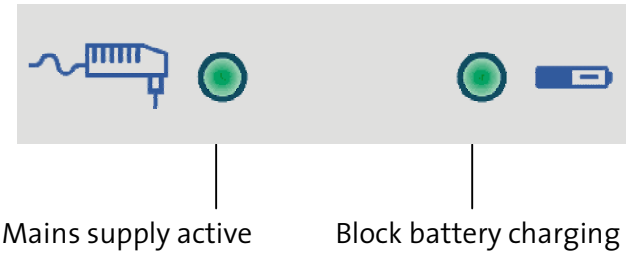


Fig. 23 Power supply LEDs

- When the LED with the power adapter symbol does not light up, but the usual monitor displays are visible, VitaGuard® is being supplied by batteries (four non-rechargeable batteries or the rechargeable block battery).

The light from the LED with the battery symbol is permanently on when the block battery is being charged in VitaGuard®. A depleted block battery takes up to six hours to recharge.

When the block battery is fully charged the LED with the battery symbol flashes every second to indicate that compensation charging is active. The block battery must therefore be fully charged at all times in the event that the power supply from the external power adapter fails.

4.5 The display

Each of the “Alarms, displays, and views during monitoring” are explained on page 57. Pressing the ◁ key in VIEW 1 takes you to the INFO screen with the current information for the doctor. Pressing it again takes you to the SYSTEM menu for the basic VitaGuard® settings.

After the monitor is switched on it can take up to twenty seconds before the first values are displayed.

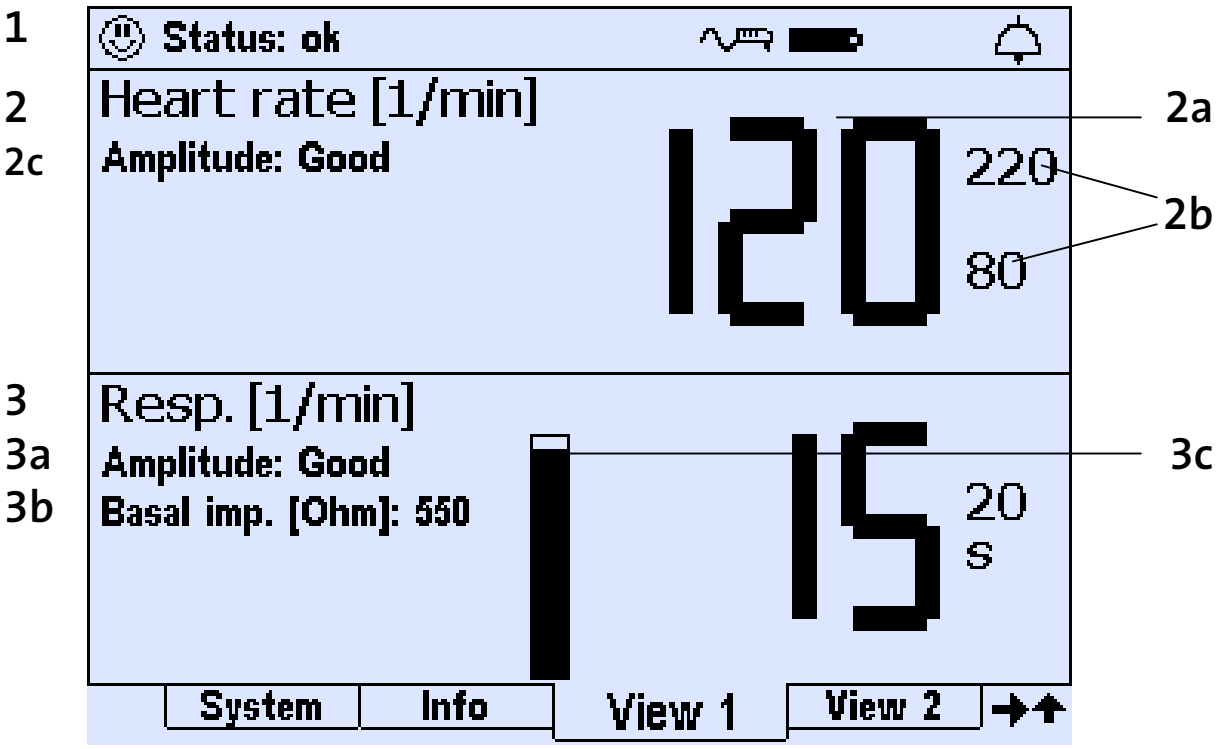


Fig. 24 Current values and alarm limits in View 1

1 The status line at the top of the display shows messages (on the left) and symbols (on the right) for the external power supply and alarm activation.

2 For all vital functions, as here HEART RATE **[2]**, the current value for each vital function **[2a]** is shown in large digits. Smaller digits to the right show the set alarm limits **[2b]**. In the HEART RATE line, the quality of the signal amplitude **[2c]** is shown on the left.

3 RESPIRATION **[3]** shows in addition on the left the quality of the amplitude **[3a]** and the basal impedance in ohms **[3b]**. This term is explained in the section “Checking the BASAL IMPEDANCE” on page 55. A respiration bar **[3c]** moves up and down synchroneously with the patient’s breathing.

5 Steps before and after monitoring

The following summary shows you all the necessary measures that need to be taken before monitoring. Also read information on how VitaGuard® is switched on and off.

The doctor and the qualified medical staff are responsible for all other important activities when "Preparing for a new patient" (see page 79).

5.1 Summary of steps before monitoring

- Insert the battery or batteries (do not switch on yet!).
- Use the external power adapter to connect VitaGuard® to the supply network (do not switch on yet!).
- Connect the ECG patient cable to VitaGuard®.
- Attach the ECG electrodes to the patient.
- Connect the ECG electrodes to the patient cable.
- Switch on VitaGuard® as explained in the next section.
- Make sure that after the monitor is switched on the indicator lamps light up briefly and a short sound is emitted by the alarm buzzers.
- Check that the alarm limits displayed are the same as those recommended by the doctor.

5.2 Switching on

Press the <Enter> key for several seconds to switch on VitaGuard®.

In the first minute of operation no acoustic signals are emitted so that you have time to check all cables. The alarm bell is crossed out for this time and the remaining time is shown next to it. Text messages, on the other hand, are shown from the beginning.

When no patient cable is connected, an acoustic reminder signal is emitted as a short tone every twenty seconds after the monitor is switched on. The technical alarms for cable and electrode monitoring are not activated until the patient cable is connected and the first plausible data have been calculated. A text message in the status line reports from the beginning that the cables are being checked.

After the device has been switched on, the following displays and signals show you that the monitoring system is fully operable.

- All indicator LEDs light up briefly. During this time the alarm LED first lights up red and then yellow.
- A brief tone is emitted to indicate that the acoustic alarm buzzer is fully operable.

If the alarm buzzer does not emit the acoustic signal after the device has been switched on, you must immediately send VitaGuard® to getemed AG or your authorized dealer for inspection. Please consult your authorized dealer for a replacement device.

Observe the patient carefully until the replacement device arrives. Bear in mind that the patient is not being monitored at this time and that no alarm will be reported in an emergency.

5.3 Switching off

Always switch off VitaGuard® in the manner described here.

1 Press the <Enter> key and keep this pressed: the message PRESS Esc KEY appears.

2 Briefly press the <Esc> key, still keeping the <Enter> key pressed, and then release both keys.

The switch off command is acknowledged by two short beeps.

Data must be stored before the device finally switches off. For this reason, VitaGuard® needs about another two seconds after the keys are released until it switches off completely.

5.4 Summary of steps after monitoring

- Switch off VitaGuard® as explained in the previous section.
- Carefully detach the ECG electrodes from the patient.
- Disconnect the ECG electrodes from the patient cable.

If the procedure concerning stored data has not been clarified during your training, then please contact your doctor.

6 Preparing for heart rate and apnea monitoring

This section is divided into the following parts.

- Safety information when monitoring heart rate and apnea
- Connecting electrodes, the patient cable, and VitaGuard®
- Technical alarm from the electrode contact monitor
- Determining the optimal electrode configuration
- ECG lead, electrode color coding
- Optimizing the heart and respiration signals – signal amplitudes in VIEW 1
- Checking the BASAL IMPEDANCE

6.1 Safety information when monitoring heart rate and apnea

Observe the following points before monitoring with VitaGuard®.

CAUTION Interference signals can prevent a heart rate alarm from being reported when under certain unfavorable conditions the monitor misinterprets these interference signals as heart signals. Interference signals can originate from the power supply or electrical apparatus in the monitor's environment. Observe the instructions under "Electromagnetic interference" on page 24.

The doctor can deactivate the APNEA ALARMS as described in the section "Settings in the RESPIRATION MENU (Settings PROTECTION OFF)" on page 103. The APNEA ALARMS are then no longer activated and OFF is displayed instead of the respiration rate. When a new age

group is selected under ADMIT NEW PATIENT, the APNEA ALARMS are reactivated together with the other factory settings.

Use only those electrodes that getemed AG or an authorized dealer has delivered or approved. Other electrodes can, in particular when monitoring apnea, cause malfunctions and in addition cause damage to the patient's skin. Read and observe the operating instructions for the electrodes.

Do not continue using damaged electrodes or cables. Do not immerse electrodes or cables in water, solvents, or liquid cleaning agents.

Store the electrodes in a cool dry place. Observe the storage instructions on the packaging.

Do not use electrodes after their expiration dates (this date is printed on the packaging, e.g. FEB2006 or 2006-02 = February 2006).

The electrodes provided are designed for short-term applications. Using the same electrodes several times can lead to malfunctions when the adhesive surface fails to adhere properly.

Do not open the electrode's packaging until shortly before the electrode is to be used. Open the packaging and remove the electrodes. Hold the sides of the electrode and peel off the transparent film. Do not pull on the electrode's cable. Avoid finger contact with the electrode's gel-coated surface as much as possible.

If you intend to reuse the same electrode a short time later, carefully reattach them to the transparent film. This helps to prevent the electrode from drying out or becoming soiled.

Use exclusively the ECG patient cable delivered by getemed AG. Connect the ECG electrodes only to the ECG patient cable and this only to the corresponding VitaGuard® socket.

CAUTION Make sure when attaching electrodes that neither the electrodes nor their plug connectors come into contact with other electrically conducting parts. There must also be no contact with

other electrically conducting parts when electrodes become detached during monitoring.

Attach the electrodes only to intact areas of skin.

Secure the electrodes and cables so that they cannot harm, strangle, or be swallowed by the patient. Always lay the patient cable at a safe distance from the patient's head and neck. Lay the patient cable when monitoring small children inside their clothing so that it exits at the foot. On larger children and adults you can, for example, lay the patient cable so that it exits between the trousers and pullover.

Place the gel-coated side of the electrode on the chosen site and carefully press it several times for a good contact.

New electrodes may be reattached several times. Peel them gently from the skin starting at the edge.

When disconnecting the electrodes from the patient cable, do not pull on the electrode's cable. Pull the plug only.

If necessary, secure the cable with an adhesive strip. The skin should be dry and free of oil and grease.

Make sure when attaching and securing the patient cable that it cannot kink. Kinking can cause damage.

Do not pull on the cable: this is unpleasant for the patient and in addition can damage the electrodes.

6.2 Connecting electrodes, the patient cable, and VitaGuard®

Insert the electrode's plug into the ECG patient cable's distributor. Note the color coding of the electrodes and the distributor's sockets.

Fig. 25 Color-coded sockets on the ECG patient cable's distributor

Insert the plug from the ECG patient cable into the socket marked with the heart and lungs symbol.

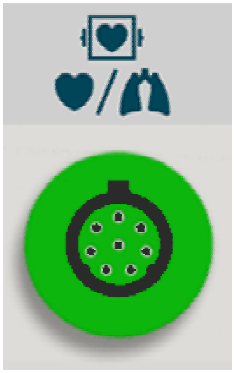


Fig. 26 Electrode socket

6.3 Technical alarm from the electrode contact monitor

The electrode contact monitor reports an alarm when:

- the electrodes have become detached,
- the electrodes are too dry (e.g. the expiration date has been exceeded or the electrodes have been used several times), giving rise to too high a value of basal impedance.

When electrodes have become detached or when the electrical resistance between the electrode and skin is too high, the respiration and ECG signals are displayed as a zero line.

When new electrodes have become detached you can reattach these by pressing them gently.

You must replace electrodes that have become detached more than once or that exhibit too high a resistance between the electrode and skin. Further explanations can be found in the section “Checking the BASAL IMPEDANCE” on page 55.

6.4 Determining the optimal electrode configuration

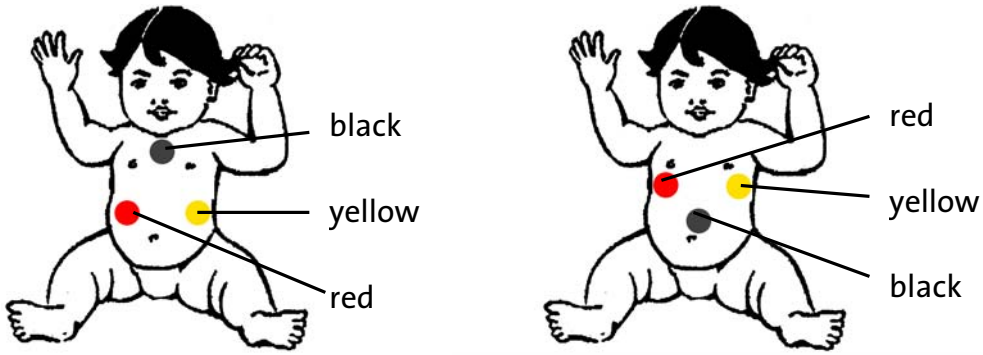
The respiration and heart signals are detected using the same electrodes. The optimal electrode configuration involves finding good signal amplitudes for both the respiration and the heart signals simultaneously.

getemed AG recommends that the responsible doctor determine the optimal electrode configuration. In most cases this configuration can be retained for the whole period of monitoring.

6.4.1 ECG lead, electrode color coding

Start with the electrode configuration depicted in Fig. 27 (see next page). First arrange

- the electrodes on infants as depicted in Fig. 27 a)
  (this electrode configuration has often proved successful because the abdominal wall of infants clearly moves synchronously with the respiration),
- the electrodes on all other patients as depicted in Fig. 27 b)



a) or b)

Fig. 27 Recommended electrode configuration

If the electrode configuration depicted in Fig. 27 does not yield a good signal quality, you can also try the alternative electrode configuration depicted in Fig. 28.

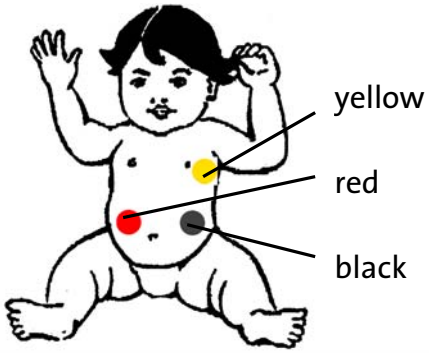


Fig. 28 Alternative electrode configuration for optimizing the heart and respiration signals

6.4.2 Optimizing the heart and respiration signals – signal amplitudes in VIEW 1

The amplitudes of the heart and respiration signals are displayed under the headings HEART RATE and RESPIRATION respectively in VIEW 1.

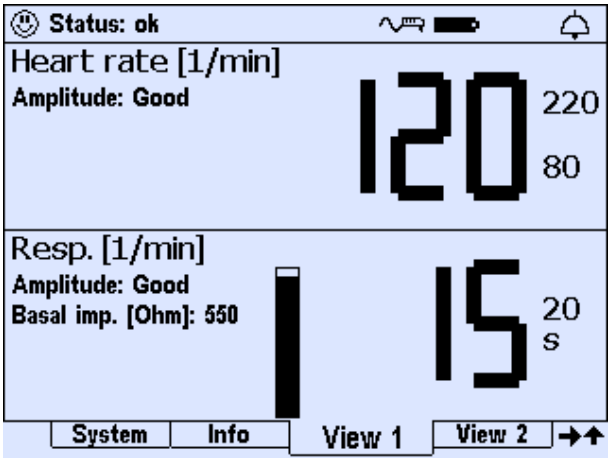
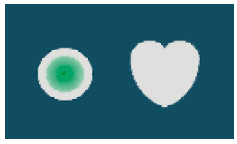


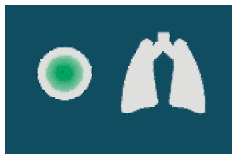
Fig. 29 Electrode signal amplitude in View 1

CAUTION When AMPLITUDE: POOR is displayed, the values for the monitored heart rate and apnea may be imprecise.

Amplitude	Meaning
POOR	the signal is not or only sporadically detected
MEDIUM	the signal is detected, but interference, e.g. due to movement, can cause false alarms
GOOD	a clear signal is detected

A correct HEART RATE is detected when the heart LED flashes synchronously with the patient's heartbeat. When the signal amplitude is GOOD or MEDIUM, there should be no deterioration in the detected heart rate when the patient moves normally.





Observe the LED with the lungs symbol and the respiration bar on the VitaGuard® display. Carefully change the positions of the red and yellow electrodes. Whenever possible, try to obtain the largest possible deflections in the respiration bar. Also, the respiration bar must move and the LED flash synchronously with the respiration.

6.5 Checking the BASAL IMPEDANCE

The basal impedance is displayed in View 1, the respiration display, and the display INFO\MEASUREMENTS: HR & RESP. The basal impedance is the sum of all impedances in the measuring circuit:

- skin and tissue impedance between the red and the yellow electrode
- impedance of the electrode-skin interface
- impedance of the electrodes themselves and the patient cable

The basal impedance slowly falls for the first few hours after the electrodes have been attached. This is caused by a reduction in the impedance at the electrode-skin interface.

The displayed basal impedance should be less than 1000 Ω. If not, wait for about fifteen minutes. When the basal impedance has still not fallen, you should use new electrodes.

When the displayed basal impedance does not lie within the specified range or when false alarms frequently occur, the doctor or the medical caregivers should observe the instructions in the section “Changing the ECG lead for signal optimization” on page 100.

7 Alarms, displays, and views during monitoring

Immediately call the emergency services when a patient remains unconscious after being shaken or addressed.

7.1 Alarm test

CAUTION: When beginning monitoring at a new site, make sure that you can clearly hear the alarm signal and quickly reach the patient. For this purpose, deliberately trigger a technical alarm.

When a patient is connected, you can deliberately trigger an alarm:

- Pull the red electrode plug out of the distributor on the ECG patient cable.

7.2 HEART RATE values based on age groups

Bear in mind that the HEART and RESPIRATION RATES drop considerably with increasing age. The doctor must check and, if necessary, adapt the alarm limits for each patient's age group.

The average heart rate of an infant is much higher than that of an adult. Accordingly, the alarm limit e.g. for bradycardia (too low a heart rate) must be set considerably higher for an infant than for an adult patient. As an orientation aid, the following table lists some medically acknowledged approximate heart rates for various age groups and stress situations.

Age group	Heart rate / min		
	Sleep	Rest	Stress (e.g. fever)
Newborns	80–160	100–180	max 220
1 week to 3 months	80–200	100–220	max 220
3 months to 2 years	70–120	80–150	max 200
2 to 10 years	60–90	70–110	max 200
10 years and older	50–90	55–90	max 200

7.3 Alarm message priorities in the status line

Fig. 30 Status line on the VitaGuard® display

Physiological alarms have high priority. The text messages of physiological alarms end with three exclamation marks.

!!!

Technical alarms have medium priority. The text messages of technical alarms end with two exclamation marks.

!!

7.4 Physiological and technical alarms

VitaGuard® generates two types of alarms: physiological and technical alarms.

- A **physiological alarm** is generated when VitaGuard® detects values that violate one or more of the set alarm limits for longer than the set period.

There are simple alarm limits, e.g. the LOWER LIMIT for the HEART RATE, and there are alarm limits based on the interaction of several monitor settings, e.g. the deviation alarms.

- A **technical alarm** is generated when monitoring is no longer reliable, e.g. when electrodes have become loose.

The reasons for incorrect values can be detached electrodes or other technical defects. When a technical alarm condition occurs, a life-threatening situation may escape detection.

When, for example, a technical alarm has occurred, yet at the same time a physiological alarm condition has been detected, the physiological alarm condition has priority and the physiological alarm is reported.

NOTE An alarm mute time of ten seconds follows a technical alarm triggered by problems with the ECG electrodes. This delay is to prevent false alarms when the physiological parameters are being recalculated. During the alarm mute time, the bell symbol in the status line is crossed out.

7.5 Differentiating physiological and technical alarm signals

The ALARM TONE PITCH can be set in the SYSTEM menu so that alarms are heard over the prevailing background noise.

The urgency or priority of an acoustic alarm can be recognized by its characteristics described in the following.

High-priority messages emit two sequences of five tones that are repeated every ten seconds.

The interval between each tone packet is two seconds. Also, there is a slightly longer interval between the third and fourth tone of each sequence.

Fig. 31 Characteristics of the high-priority acoustic alarm signal

Medium-priority messages emit a sequence of three tones which is repeated every 5.2 seconds.

7.6 Acoustic information signals

If wished, the alarm unit next to the display can produce a short acoustic signal to accompany each heartbeat or each breath.

7.6.1 Information signals from the alarm unit next to the display

After the monitor is switched on, an acoustic reminder signal is emitted every twenty seconds until all electrodes are connected and plausible data have been detected.

7.6.2 Information signals from the sound aperture between the sockets

A pulsating tone is emitted if the external power adapter is disconnected and no batteries are installed.

7.7 The visual alarm signals

- A high-priority alarm, i. e. physiological alarm, causes the alarm LED to flash red.

- A medium-priority alarm, i. e. technical alarm, causes the alarm LED to flash yellow.

7.8 Status line displays

During monitoring the status line is displayed in all views.

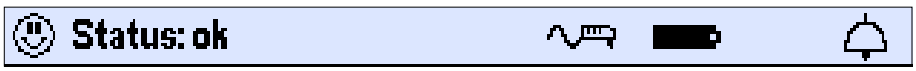


Fig. 32 The status line displayed in all views

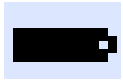
The monitor's text messages appearing on the left are explained in detail in the section "Alarm messages – meanings and other information" on page 63. On the right of the status line are three symbols.

- Power supply

The power supply symbol indicates whether the NA3000-2 external power adapter or the automobile power supply adapter is connected. When a power adapter is connected, the symbol appears as illustrated on the right. Otherwise the symbol is crossed out.

- Battery voltage indicator

The battery voltage indicator depicts the voltage from the batteries. When the block battery is being recharged this symbol is animated, i. e. a filling animation is displayed.



- Alarm indicator

When you interrupt an acoustic alarm by pressing the <Esc> key, the bell symbol is crossed out. To the left of the bell, the remaining alarm mute time is displayed in seconds. This mute time applies only to the current alarm type.

When a new alarm condition is detected, the acoustic alarm is emitted before the alarm mute time has expired.

Pressing the <Esc> key a second time immediately ends the ALARM MUTE TIME.

The alarm bell outline indicates that all acoustic alarm signals are enabled.

In the event of an alarm, the alarm bell is filled out and flashes.

7.9 Heart rate and apnea monitoring

After the monitor is switched on, it may take up to twenty seconds before the first values are displayed.

7.9.1 Heart rate alarms

The currently set alarm limits are always displayed.

When the displayed HEART RATE

- falls below the LOWER LIMIT for longer than the set BRADYCARDIA DELAY or
- exceeds the UPPER LIMIT for longer than the set TACHYCARDIA DELAY
- or when the ECG signal is not detected for longer than the set ASYSTOLE DELAY

VitaGuard® emits an acoustic alarm signal and displays the corresponding message. The violated alarm limit and the alarm LED flash.

Go immediately to the patient when an alarm is reported and check the patient's condition.

The alarm is ended automatically when the heart rate returns within the permitted limits.

Deviation alarms can also be activated in addition to the alarms based on permanently set limits.

7.9.2 Apnea alarms

An alarm is reported when apnea, i.e. respiratory arrest, is detected for longer than the set APNEA DELAY. An alarm message then appears on the display, the alarm LED flashes, and an acoustic warning is emitted.

Go immediately to the patient when an alarm occurs and check the patient's condition. When the patient resumes breathing, the alarm is switched off automatically. Both the delay time and the alarm LED continue to flash to show that apnea has occurred for longer than the set APNEA DELAY. Pressing the <Esc> key stops the flashing.

7.9.3 Technical heart rate and apnea alarms

The section "Table of technical alarm messages" on page 65 can be consulted for the technical alarm signals and the recommended troubleshooting procedure. The heart rate and apnea monitors display technical alarms with the corresponding messages. Until the problem has been eliminated, the heart and respiration rates are replaced by a question mark symbol.

7.10 Alarm messages – meanings and other information

The tables in this section list in alphabetical order all the text messages that can appear on the VitaGuard® display together with more detailed explanations and troubleshooting hints.

7.10.1 Order of equal-priority alarm conditions

The numbers in the No. column on the right indicate the internal priorities that VitaGuard® uses to process the respective messages. This is of importance to the doctor only.

7.10.2 Table of physiological alarm messages

Physiological alarms are reported with high priority.

Message	Meaning	Information	No.
Apnea detected!!!	A respiration signal has not been detected for longer than the set APNEA DELAY.	When there is no apnea: - The electrodes are badly placed, i.e. the signal is too small to be detected. - Cardiogenic artifacts are superimposed on the respiration signal so that it is rejected. - The monitor, cable, or electrode is defect. - The set APNEA DELAY is too short.	10
ECG amplitude low!!!	The monitor could not detect the ECG signal for longer than the set ASYSTOLE DELAY.	When there is no asystole (cardiac arrest or delay): - The electrodes are badly placed. - The ECG signal is too small to be detected. - The monitor, cable, or electrode is defect.	5
Heart rate and apnea!!!	A heart rate alarm and an apnea alarm have occurred simultaneously.	See the messages and information for “Heart rate too high/ too low” and "Apnea detected”.	3
Heart rate too high!!!	The calculated heart rate exceeds the set UPPER LIMIT for longer than the set TACHYCARDIA DELAY.	When there is no tachycardia: - T wave peaks are interpreted as R waves so that the calculated heart rate is too high. - The electrodes are badly placed. - Artifacts caused by excessive movement trigger false alarms. - 50 Hz or other sources of electromagnetic interference trigger false alarms: suspected interference sources must be removed - The electrode has become detached. - The monitor, cable, or electrode is defect. - The set UPPER LIMIT is too low.	7

Message	Meaning	Information	No.
Heart rate too low!!!	The calculated heart rate falls below the set LOWER LIMIT for longer than the set BRADYCARDIA DELAY.	When there is no bradycardia: - Heartbeats are not detected. - The electrodes are badly positioned. - Abnormal beats, e.g. extrasystoles, are not detected. - The electrode has become detached. - The monitor, cable, or electrode is defect. - The set LOWER LIMIT is too high.	6
Heart rate drop detected!!! (when activated)	The current heart rate falls below the value based on the set AVERAGING INTERVAL by more than the percentage deviation value set under TREND DEVIATION (–).	When there is no heart rate drop: - The heart rate and/ or the average heart rate is incorrectly calculated for the reasons given under “Heart rate too low”	11
Heart rate rise detected!!! (when activated)	A heart rate rise is detected in the same manner as a heart rate drop, but TREND DEVIATION (+) is used instead.	When there is no heart rate rise: - The heart rate and/ or its average is incorrectly calculated for the reasons given under “Heart rate too high”.	12

7.10.3 Table of technical alarm messages

Message	Meaning	Cause or elimination	No.
Check ECG cable!!	The monitor discovers that the ECG cable is not connected.	- Check the ECG cable.	22
Check electrodes!!	The monitor discovers that one or more electrodes are not connected.	- Check the electrodes: If this message persists, use new electrodes or replace the ECG cable.	23
Check power adapter!!	The measured voltage from the power adapter is less than 8 V or greater than 10 V.	- Check that the stipulated power adapter is being used. - Check and, if necessary, replace the NA3000-2 power adapter.	16

Message	Meaning	Cause or elimination	No.
Conflicting HR limits!!	The heart rate's LOWER LIMIT has been set higher than the UPPER LIMIT.	- Correct the heart rate limits.	19
Corrupted ECG signal!!	The ECG signal is corrupted too strongly by 50 Hz interference signals from the supply network.	- Attach the electrodes as symmetrically as possible. - Replace the electrodes. - Select the "I YE-RD, 3" lead. - Proceed in accordance with the section "Electromagnetic interference" on page 24.	24
Hardware fault!!	The monitor has detected an internal fault.	- Switch off the monitor, wait for thirty seconds, and switch it back on: if this message persists, the monitor is defect.	14
Internal data error!!	The internal software monitor has detected a data transfer error.	- Switch off the monitor, wait for thirty seconds, and switch it back on: if this message persists, the monitor is defect.	18
No cables connected!!	The monitor discovers that the patient cable is not connected.	- Connect the patient cable.	21
No power adapter !!	The power adapter has been disconnected.	- Reconnect the external power adapter or press the <Esc> key.	17
Recharge battery!!	The battery voltage is too low: the monitor can no longer operate reliably	- Operate the monitor with the external power adapter to recharge the block battery, or insert non-rechargeable batteries.	32
Replace batteries!!	The battery voltage is too low: the monitor can no longer operate reliably.	- Insert new batteries or a new block battery or operate the monitor with the external power adapter.	33

7.11 Table of information messages

Message	Cause	Meaning	No.
Calculating heart rate	The current heart rate cannot be displayed while it is being calculated.	The current heart rate is displayed after it has been calculated.	37
Internal battery too low	The internal battery for alarms during a power failure is depleted.	- The monitor is defect i. e. the internal battery needs to be replaced by a technician.	39
Status: ok	No messages		40

8 Alarm and monitor settings

The functions described in this section can be accessed only when the doctor has set SETTINGS PROTECTION to LIMITED in the SYSTEM menu. This setting requires a code.

The function ADMIT NEW PATIENT in the SYSTEM menu overwrites all earlier settings.

The set alarm limits and other monitor parameters are stored and retained when the monitor is switched back on after a battery change.

8.1 Safety instructions for the alarm settings

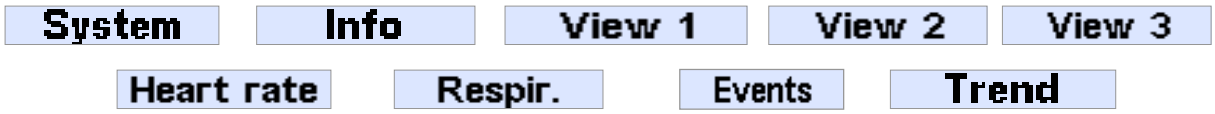
It is important that the doctor responsible sets new alarm limits and monitor parameters for each patient and for each new medical situation. Never change alarm limits without consulting the treating doctor.

Never set the alarm limits to extreme values that render the monitoring system useless.

When you have been given a code for changing alarm limits, it is important that you treat this code as confidential. Life is in danger when alarm limits are not adapted specifically to each and every patient.

8.2 Summary of views and menus

The views presented here are intended to provide extensive information on the monitoring situation. When SETTINGS PROTECTION is set to LIMITED, they can be accessed with the direction keys ◁ and ▷.



The keys △ and ▽ let you access more detailed information and enter menus for changing monitor settings.

- The △ or ▽ key takes you from the SYSTEM view to the SYSTEM menu. The first setting is highlighted.
- The △ or ▽ key leafs through pages on the INFO display.
- The △ or ▽ key takes you from VIEW 1, 2, or 3 to the menu "MANUAL DATA STORAGE or TRANSMIT DATA". This is explained in the corresponding section on page 94.
- The SpO_2, HEART RATE, and RESPIRATION displays each feature a menu for adjusting the respective settings and can be accessed with the △ or ▽ key. The first setting is highlighted.
- The △ or ▽ key takes you from the EVENTS or TRENDS views to detailed views, WAVEFORMS, and TRENDS.

8.3 Additional views

When the doctor has configured VitaGuard® so that also the caregivers can change settings, i.e. SETTINGS PROTECTION is set to LIMITED, VIEWS 2 and 3 are also activated in addition to VIEW 1. VIEW 1 is explained in the section "The display" on page 44.

8.3.1 VIEW 2 – Large data presentation and waveforms

VIEW 2 displays in large digits the current values for the monitored vital functions and, on the right in smaller digits, the set alarm limits.

Also, each section on the left presents a waveform of the monitored vital function.

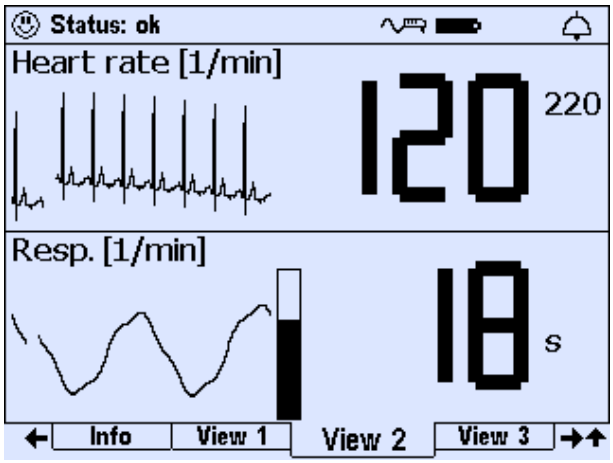


Fig. 33 View 2

8.3.2 VIEW 3 – Smaller data presentation and waveforms

The top half of VIEW 3 displays the current measured values and the alarm limits.

The bottom half of VIEW 3 displays the waveforms over a longer interval than VIEW 2.

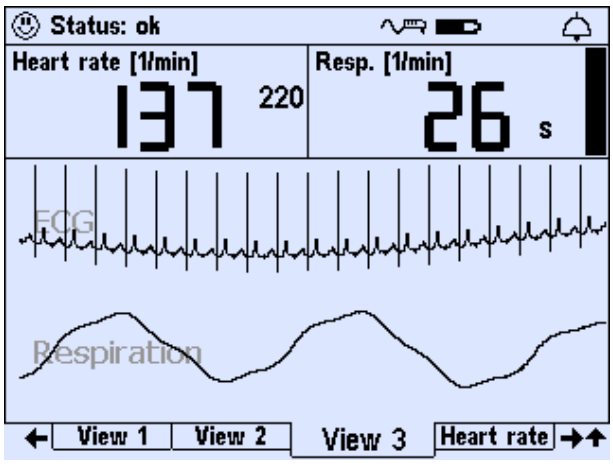


Fig. 34 View 3

8.4 Changing the settings

Use the direction keys to highlight a menu option or an entry in this option. Once you have highlighted the option you want, press the <Enter> key to change it. When you do not want to keep your changes, press the <Esc> key.

The △ key takes you to the menus. The first entry in the list is highlighted. Use the ▽ key to highlight the setting LCD BRIGHTNESS (“Changing multiple-component settings” is explained on page 87 for the doctor and qualified medical staff).

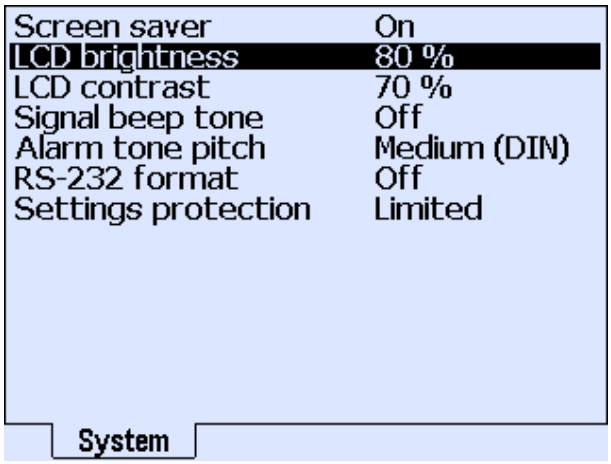


Fig. 35 Menu system, “LCD brightness: 80%” highlighted

Press the <Enter> key. A window appears where you can change the old value.

Use the △ and ▽ keys to change the highlighted value.

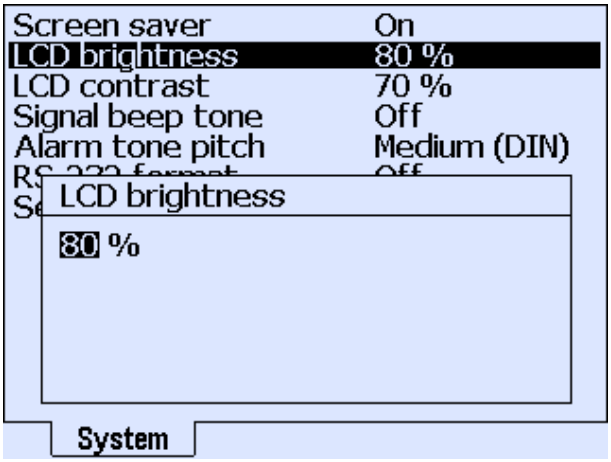


Fig. 36 System, “LCD brightness” highlighted in the change window

Pressing the <Enter> key after changing a value causes a prompt to appear with ACCEPT: No highlighted. Press the ◁ key to highlight ACCEPT: YES.

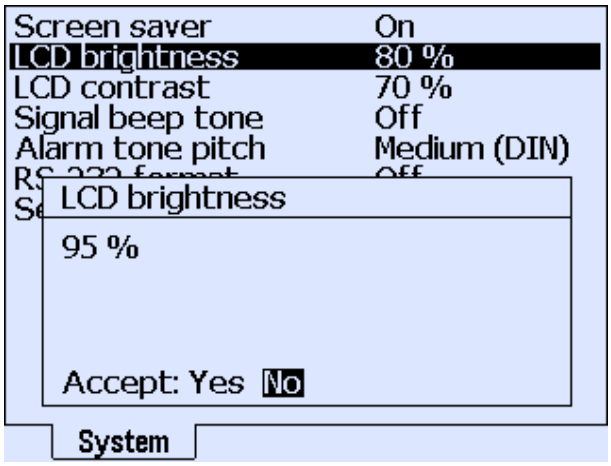


Fig. 37 System, accept change to LCD brightness highlighted

Confirming the prompt ACCEPT: YES with the <Enter> key displays the changed value in the list. To exit the menu press the <Esc> key.

8.5 SYSTEM menu – general settings

NOTE You can familiarize yourself with the menus without changing values. Simply press the <Esc> key to exit each menu and submenu without saving changes.

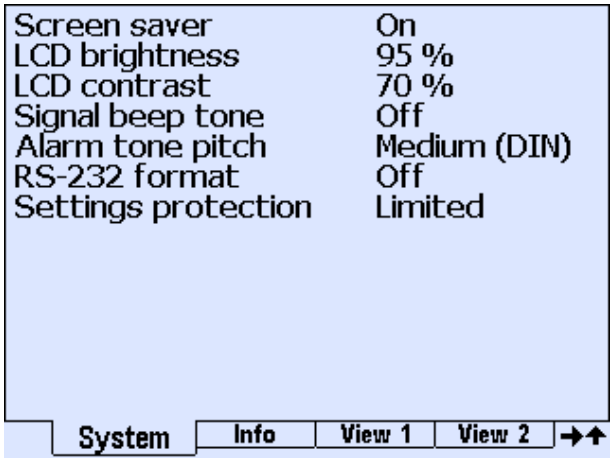


Fig. 38 System menu – general settings

8.5.1 SYSTEM\ SCREEN SAVER (OFF/ ON)

When SCREEN SAVER is set to ON, an animation appears on the display when no key has been pressed for five minutes.

When you press a key or an alarm is triggered, the previous mask is displayed again.

8.5.2 SYSTEM\ LCD BRIGHTNESS

You can set the LCD BRIGHTNESS from 0% to 100% in steps of 5%. When 0%, the display's backlight illumination is switched off. The factory setting is 95%.

8.5.3 SYSTEM\ LCD CONTRAST

You can set the display's contrast from 0% to 100% in steps of 5%. The factory setting is 70%.

8.5.4 System\ Signal beep tone

You can configure the monitor to emit a brief signal tone with every detected respiration (Respiration) or with every detected heartbeat (Heart/ pulse beat).

When this tone disturbs the patient or caregivers, choose the setting Off.

The factory setting is Off.

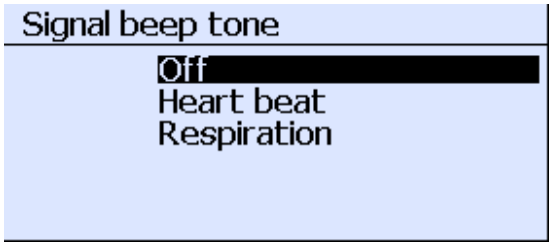


Fig. 39 System\ submenu "Signal beep tone"

8.5.5 System\ Alarm tone pitch

You can set the pitch of the acoustic alarm signals to Low, Medium, or High so that they can be heard over the expected background noise. The DIN settings (DIN) match the alarm tone characteristics as described from page 59 on in the section "Differentiating physiological and technical alarm signals". As an alternative, you can set the alarm tone characteristic (gtm) as familiar from other getemed devices.

The factory setting is Medium.

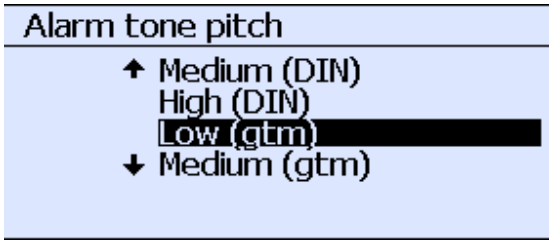


Fig. 40 System\ submenu "Alarm tone pitch"

8.5.6 System\ RS232 format

This submenu lets you assign the format for online data output from the AUX serial port.

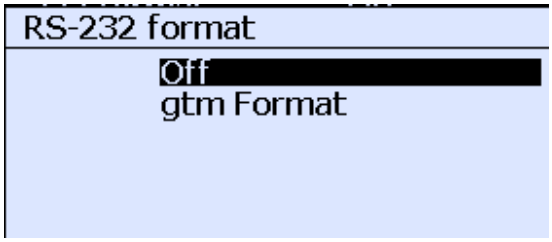


Fig. 41 System\ RS232 format

8.5.7 System\ Settings protection On, Limited, Off

The codes that protect the alarm defaults from unauthorized changes must be given by the doctor to those persons only whom the doctor judges to be adequately informed about monitoring and their responsibility for the patient. The doctor should point out that the code must be treated as confidential, that settings should be changed at the doctor's request only, and that all changes must be confirmed by the doctor.

VitaGuard® provides the following three settings for Settings protection.

- **Settings protection ON** deactivates all options to change monitor settings. The display presents only View 1, the Info display, and the System menu.
- **Settings protection Limited** enables access to all views and menus. Of all the monitor settings, however, only the alarm limits can be changed.
- **Settings protection Off** enables all views and menus and allows changes to all monitor settings.

The factory setting is Settings protection Limited.

After highlighting the function Settings protection, press the <Enter> key to open a submenu.

- This submenu always displays Settings protection as "00" irrespectively of the current setting. Pressing the <Enter> key activates Settings protection.
- When you enter a code Settings protection appears as Limited.
- When you enter a different code, Settings protection appears as Off.

When the wrong code has been entered three times Settings protection cannot be so easily deactivated. In this case, consult your authorized dealer.

8.6 HEART RATE display and menu

The ▷ key takes you from VIEW 1, 2, or 3 to the heart rate display. From here you can open the menu with the △ or ▽ key. When a row is highlighted, press <Enter> to change the corresponding value.

8.6.1 HEART RATE display

The top half of the display presents:

1 the status line

2 the current values with the set alarm limits

3 the current three-minute trends that update the last value every two seconds

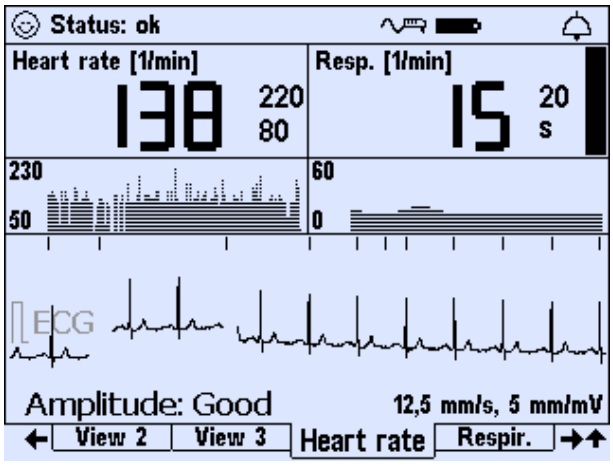


Fig. 42 Heart rate display

The heart rate trend display presents the heart rate over the last three minutes. This display varies with the set age group:

	0 TO 2 YEARS	2 TO 6 **YEARS**	>6 YEARS
HEART RATE TREND DISPLAY [PER MIN]	between 230 and 50	between 180 and 50	between 150 and 45

The bottom half of the display presents the ECG. A small vertical bar above the ECG indicates every detected heartbeat. Under the ECG you can see the evaluated amplitude of the ECG signal known from VIEW 1.

8.6.2 HEART RATE menu – alarm settings (SETTINGS PROTECTION LIMITED)

The HEART RATE menu lets you view and, if necessary, change the current heart rate settings. You may have to adapt the default age

group alarm limits to the current patient. These settings can be changed only when SETTINGS PROTECTION has been set to LIMITED in the SYSTEM menu.

Different heart rate alarm limits can be set as the default values for each age group:

Default	0 TO 2 YEARS	2 TO 6 YEARS	>6 YEARS
LOWER HEART RATE LIMIT [/MIN]	80	60	55
UPPER HEART RATE LIMIT [/MIN]	220	150	140

In the event of persistent false alarms, a different lead can be set in the HEART RATE menu as explained in the section "Changing the ECG lead for signal optimization" on page 100.

The heart rate's LOWER LIMIT can be set from 30 to 180 beats and the heart rate's UPPER LIMIT from 100 to 255, each in steps of five beats per minute.

Factory settings are shown in bold type.

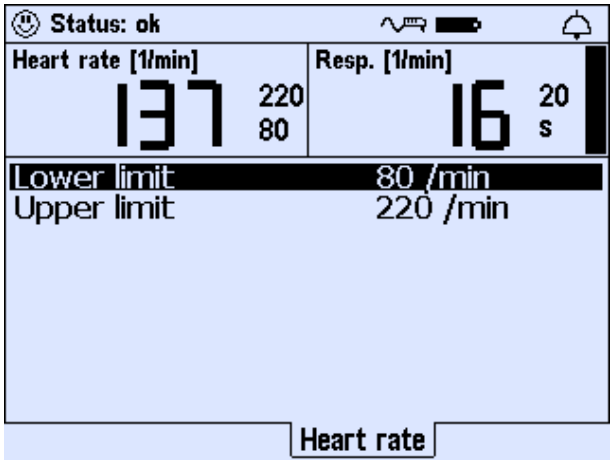


Fig. 43 Heart rate menu for viewing and setting alarm limits

LOWER LIMIT (heart rate) ..... 30, 35 ... **80** ... 175, 180/min
Lower limit for the heart rate; an alarm is reported when the heart rate falls below this limit for longer than the set BRADYCARDIA DELAY

UPPER LIMIT (heart rate) ..... 100, 105 ... **220** ... 250, 255/min
Upper limit for the heart rate; an alarm is triggered when the heart rate exceeds this limit for longer than the set TACHYCARDIA DELAY

8.7 RESPIRATION display and menu

The ▷ key takes you from VIEW 1, 2, or 3 to the RESPIRATION display. From here you can open the menu with the △ or ▽ key. Having highlighted a row, press <Enter> to change the corresponding value.

8.7.1 RESPIRATION display

The top half of the display presents:

1 the status line

2 the current values with the set alarm limits

3 the current three-minute trends that update the last value every two seconds

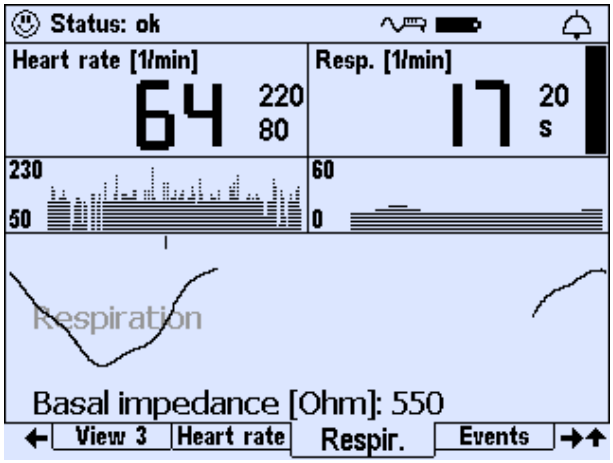


Fig. 44 Respiration display, respiration graph

The RESPIRATION trend display presents the respiration rate over the last three minutes. This display varies with the set age group:

	0 TO 2 YEARS	2 TO 6 **YEARS**	**>** 6 **YEARS**
RESPIRATION RATE TREND DISPLAY [PER MIN]	between 0 and 60	between 0 and 60	between 0 and 30

The bottom half of the RESPIRATION display presents the respiration waveform. A small vertical bar above the respiration waveform indicates every detected respiration signal. Under the respiration curve you can see the respiration signal's BASAL IMPEDANCE in ohms, as in VIEW 1.

The displayed respiration rate is not used in the alarm assessment and is calculated and displayed only when the respiration signal exhibits an adequate amplitude and is relatively free of movement artefacts. Otherwise a question mark is displayed. This has no negative effects on either the alarm function or the detection of central apneas.

8.7.2 Respiration menu – alarm settings (Settings protection Limited)

These settings can be changed only when Settings protection is set to Limited in the System menu.

Factory settings are shown in bold type.

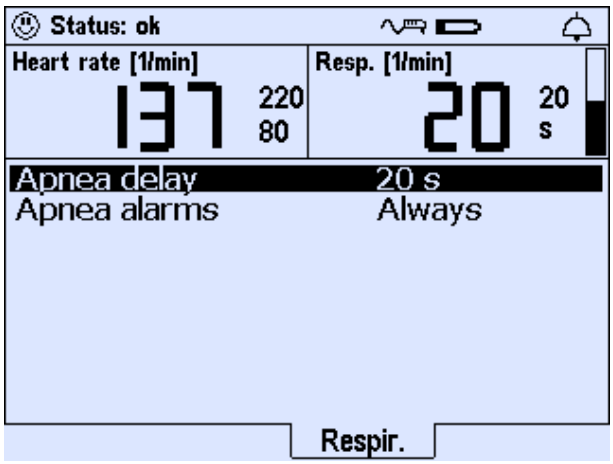


Fig. 45 Respiration menu for viewing and setting alarm limits

Apnea delay ..... 8, 10 ... **20** ... 32, 34 seconds
VitaGuard® interprets apnea and triggers an alarm when a respiration signal or movement is not detected and Apnea delay is exceeded. The doctor must have set Apnea alarms to Always.

Apnea alarms ..... Off/**Always**

CAUTION A deactivated apnea monitor can no longer detect apnea!

Off and **Always** switches off and on the apnea monitor. In both cases the respiration waveform is displayed and stored.

9 Information for the doctor and qualified medical staff

The treating doctor is responsible for monitoring with VitaGuard®. This also applies to ambulatory monitoring.

This section contains all safety and settings information that only the treating doctor can make decisions on. Remember that all the information and instructions in the sections “Intended use” on page 14 and “Safety” on page 20 must also be observed.

Only getemed AG personnel or authorized dealers certified by getemed AG as medical product advisers in accordance with § 31 MPG (German Medical Products Act) may instruct the doctor and the qualified medical staff on how to handle and use VitaGuard®. This certification is awarded only to those persons that have received adequate training from getemed AG for its products.

9.1 Safety instructions

The safety instructions in this section address special technical and medical issues that are of particular importance to the doctor and qualified medical staff.

9.1.1 Preparing for a new patient

When more than one VitaGuard® monitor with differing settings are used in the same environment, there is a risk of mixing monitors and a particular patient may be monitored with unsuitable settings. For this reason check the currently set alarm limits every time the monitor is switched on.

It is important that VitaGuard® is configured so that false alarms are avoided to the greatest possible extent. Frequent false alarms can prove detrimental to the alertness of caregivers.

When VitaGuard® is to be used for a new patient, the doctor or the qualified medical staff are obliged to take the following important precautionary measures.

- Place used consumables such as electrodes in a plastic bag before disposing of them in household or medical waste.
- Clean the device and disinfect all cables (e.g. as described in the guidelines from the Robert Koch Institute).
- Insert new batteries or a fully charged block battery.
- Select the age group in SYSTEM\ ADMIT NEW PATIENT as explained under “SYSTEM\ ADMIT NEW PATIENT – restoring factory settings” on page 88.
- Check that the monitor settings are suitable for the patient and, if necessary, adapt them.
- Consider that the monitor settings may need to be changed at a future date and, as appropriate, arrange appointments to change these settings.
- Check that the acoustic alarm signal is loud enough to be heard over the prevailing or expected noise levels in the monitor’s environment.
- When necessary, set SETTINGS PROTECTION to LIMITED.
- When necessary, train caregivers in the necessary resuscitation measures.

9.1.2 Connections to the USB and AUX ports

The USB port is designed to transfer data to a PC. The AUX port can interface with a modem for remote data transfer.

Observe the standard DIN EN 60601-1-1 for connections to systems consisting of multiple medical devices and to systems consisting of medical and non-medical devices.

A device must comply with the regulations under DIN EN 60601-1 for medical devices or under DIN EN 60950 for communication technology devices before it is connected to the USB or AUX ports. In addition, the leakage current from the VitaGuard® must be measured as stipulated in the standard DIN EN 60601-1-1. This leakage current must not exceed 100 µA. Only qualified medical device technicians can check whether the leakage current conforms to the standards.

When several devices are connected to each other, the individual leakage currents can add up and may pose a risk to the patient.

Do not connect printers, cameras, scanners, or other devices.

9.1.3 VitaGuard® and other medical devices

When VitaGuard® is to operate at the same time as a defibrillator, the monitoring results may be invalid for a short time. In addition, defibrillation can damage the cables. Check the monitoring system after defibrillation.

Bear in mind that an external defibrillation pulse can be attenuated. A test in accordance with DIN EN 60601-2-49 showed that defibrillation pulses emitted during monitoring are attenuated by less than 10 %.

Do not use VitaGuard® in conjunction with HF surgical equipment, TENS devices, or nerve stimulators.

VitaGuard® correctly interprets pacer pulses with amplitudes greater than 5 mV, so VitaGuard® can be used on patients with pace makers.

Warn your pacemaker patients that the displayed heart rate may possibly be affected by stimulating pulses. Point out to the caregivers that they must carefully observe pacemaker patients.

Do not operate VitaGuard® near MRI devices (magnetic resonance imaging) or other systems that generate strong electromagnetic fields. The electrode leads, for example, can heat up by induction, causing burns under the electrodes and fire in the cables. The strong magnetic fields generated by magnetic resonance image devices can cause permanent damage to VitaGuard®.

9.2 INFO display

The INFO display quickly presents the doctor with a summary of the monitor settings and data. Other INFO windows can be accessed with the direction keys △ and ▽.

The current page number and the total number of pages are displayed in the top right. For example, “1/10” means “the first of ten pages”.

9.2.1 INFO\ LAST STATUS MESSAGES

The last status messages provide information on the directly preceding monitoring period. Here you can see when and why a message appeared.

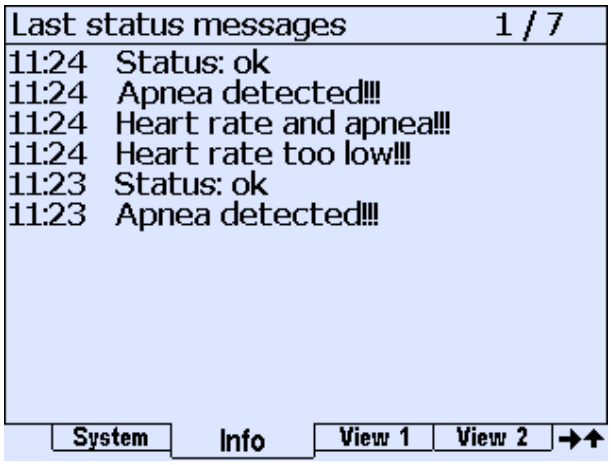


Fig. 46 Info\ Last status messages

9.2.2 Info\ General

- Internal battery

This displays the state of the Internal battery permanently installed in VitaGuard®.

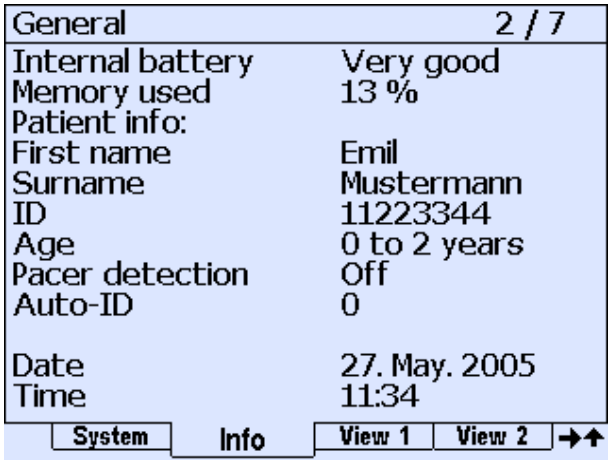


Fig. 47 Info\ General

- Patient name/ Patient ID

The patient's name and ID are displayed when VitaWin® has transferred these from a PC to VitaGuard® or when they have been keyed in as explained in the section "System\ Admit new patient – restoring factory settings" on page 88.

- Age

This displays the age group that has been set as explained in the section "System\ Admit new patient – restoring factory settings" on page 88.

- Pacer detection

When the patient has a pacemaker, set Pacer detection in the Heart rate menu to On: this prevents the monitor from processing stimulating pacemaker pulses as R waves.

- Auto-ID

This displays the ID number that is automatically assigned every time the Admit new patient function is executed.

- Date, time

This displays the date and time of the internal clock which can be set in the System menu.

9.2.3 Info\ Measurements: HR & Resp.

Info\ Measurements: HR & resp. displays the various average heart rate values calculated since the monitor was switched on. These values are lost when the monitor is switched off.

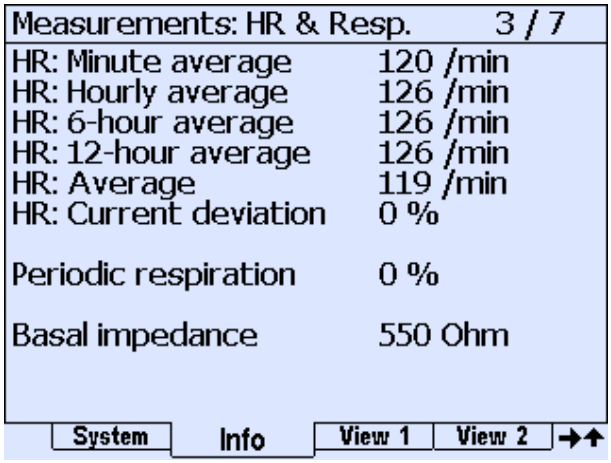


Fig. 48 Info\ Measurements: HR & Resp.

HR: Average is calculated over of the Averaging interval set in the Heart rate menu.

HR: Current deviation shows how much the current heart rate deviates from the Average in percent.

This deviation is used for triggering deviation alarms when Heart rate alarms has been set to Limits & trends in the Heart rate menu. This setting is restored as the factory setting when the Admit new patient function is executed in the System menu.

Periodic respiration displays the time in percent that Periodic respiration has been detected since the monitor was switched on. This value is displayed only when the function Periodic respiration is set to On in the Respiration menu and when Age group is set to 0 to 2 years under System\ Admit new Patient.

Basal impedance displays the value measured between the yellow and the red electrode (see “Checking the basal impedance” on page 55).

9.2.4 Info\ Settings: Heart rate

This window presents all the settings for heart rate monitoring that are not shown in Views 1 to 3.

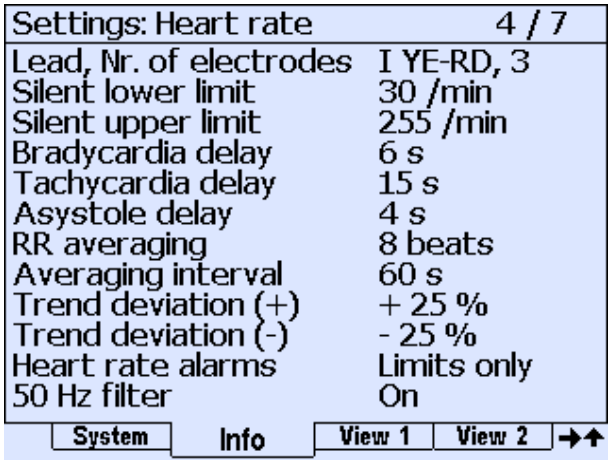

Settings: Heart rate 4 / 7
Lead, Nr. of electrodes I YE-RD, 3
Silent lower limit 30 /min
Silent upper limit 255 /min
Bradycardia delay 6 s
Tachycardia delay 15 s
Asystole delay 4 s
RR averaging 8 beats
Averaging interval 60 s
Trend deviation (+) + 25 %
Trend deviation (-) - 25 %
Heart rate alarms Limits only
50 Hz filter On
System
Info
View 1
View 2

Fig. 49 Info\ Settings: Heart rate

9.2.5 Info\ Settings: Apnea monitor

This window presents all the settings for apnea monitoring that are not shown in Views 1 to 3.

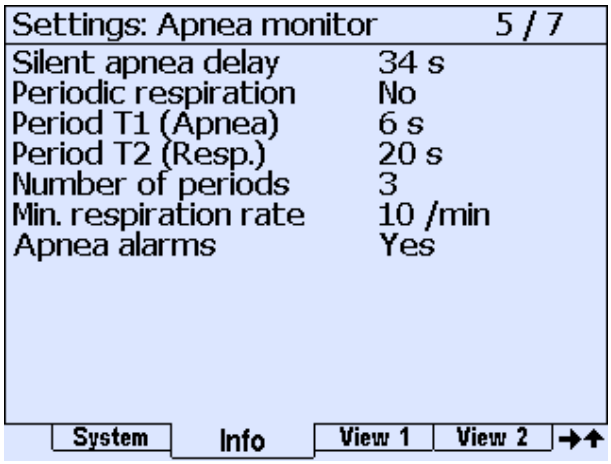


Fig. 50 Info\ Settings: Apnea monitor

9.2.6 Info\ Memory/ Internet

This displays the current Memory used and the total Memory size.

Also displayed is Telephone, i.e. the modem number that the monitor automatically dials for remote data transfer. This telephone number must be loaded by the evaluation software VitaWin® and cannot be edited directly in the monitor.

Here you can also view the details for transferring data as an e-mail attachment.

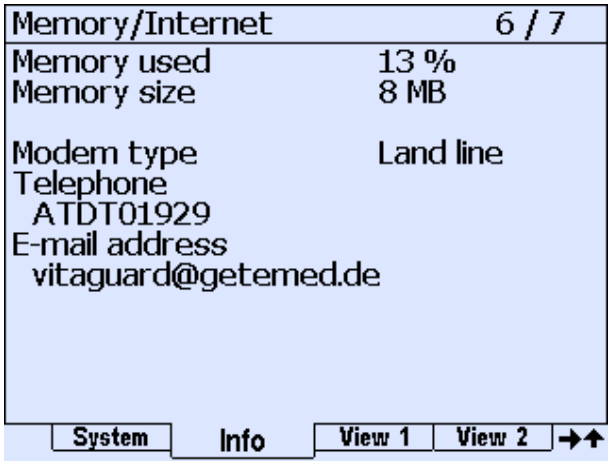


Fig. 51 Info\ Memory

9.2.7 Info\ Versions

Info\ Versions displays the software and hardware version numbers followed by the monitor's serial number (SN).

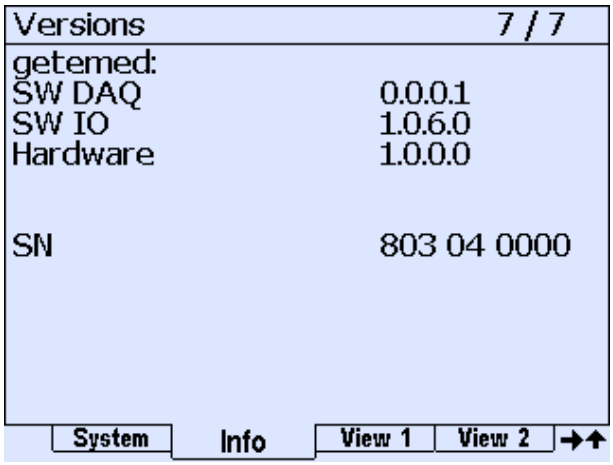


Fig. 52 Info\ Versions

9.3 Settings in the SYSTEM menu (SETTINGS PROTECTION OFF)

When SETTINGS PROTECTION is switched off in the SYSTEM menu, the doctor can configure VitaGuard® for specific monitoring requirements.

Use the direction keys to highlight an entry. When you want to change the entry, press the <Enter> key. Pressing the <Esc> key discards any changes without saving.

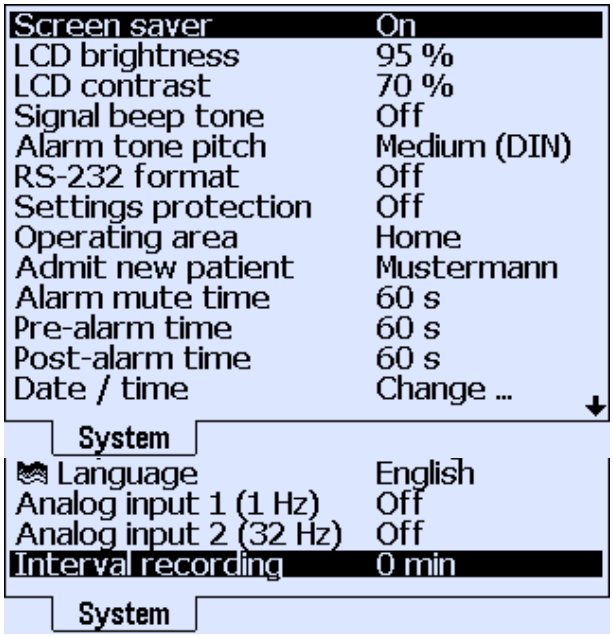


Fig. 53 Separately protected settings in the System menu

9.3.1 Changing multiple-component settings

The following example for changing the date and time in the SYSTEM menu is intended to explain how you can change system settings consisting of several components.

Use the ▽ key to highlight the entry DATE/ TIME.

Press <Enter>. A window appears for changing the old entry.

Use the keys ◁ and ▷ to highlight the component you want to change.

The highlighted value is changed with the keys △ and ▽.

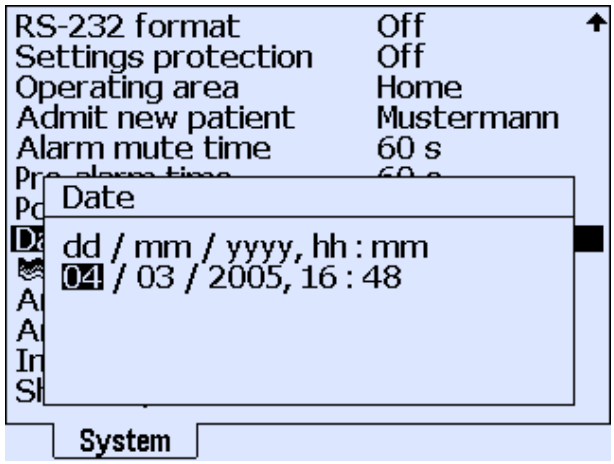

RS-232 format Off
Settings protection Off
Operating area Home
Admit new patient Mustermann
Alarm mute time 60 s
Date
dd / mm / yyyy, hh : mm
04 / 03 / 2005, 16 : 48
System

Fig. 54 System\ Date/ time

After changing a value, pressing the <Enter> key a second time causes a prompt to appear with ACCEPT: NO highlighted. Press the ◁ key to highlight ACCEPT: YES. Confirming the prompt ACCEPT: YES with the <Enter> key displays the changed value in the list. To exit the menu press the <Esc> key.

9.3.2 SYSTEM\ OPERATING AREA: HOME OR CLINIC

OPERATING AREA lets you decide whether the value you have entered for SETTINGS PROTECTION is retained the next time VitaGuard® is switched on.

When you select HOME, SETTINGS PROTECTION is ON when the device is next switched on.

When you select CLINIC, SETTINGS PROTECTION is set to the selected value when the device is next switched on.

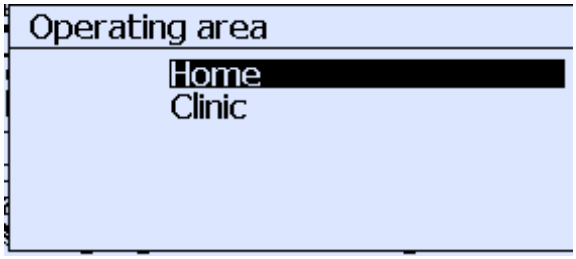


Fig. 55 Operating area: Home or Clinic

9.3.3 SYSTEM\ ADMIT NEW PATIENT – restoring factory settings

IMPORTANT: This deletes all stored data and all monitor settings for a specific patient.

Check that the new monitor settings are suitable for the patient.

All data are deleted and all user settings are restored to the factory values, so you are prompted whether you want to CONTINUE. Press the ◁ key to highlight ACCEPT: YES and then the <Enter> key.

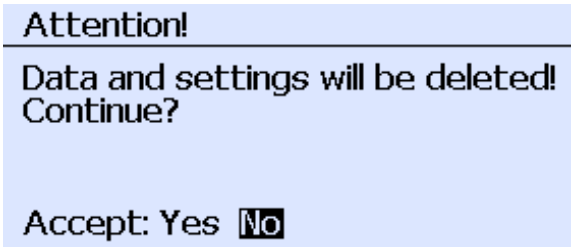


Fig. 56 Warning before changes under System\ Admit new patient

The submenus for ID, FIRST NAME, and SURNAME are displayed one after the other.

Use the ◁ and ▷ keys to position the cursor.

Use the △ and ▽ keys to enter letters and numbers.

Press the <Enter> key after you have entered your data in each submenu.

These inputs are optional and can be skipped by pressing the <Enter> key.

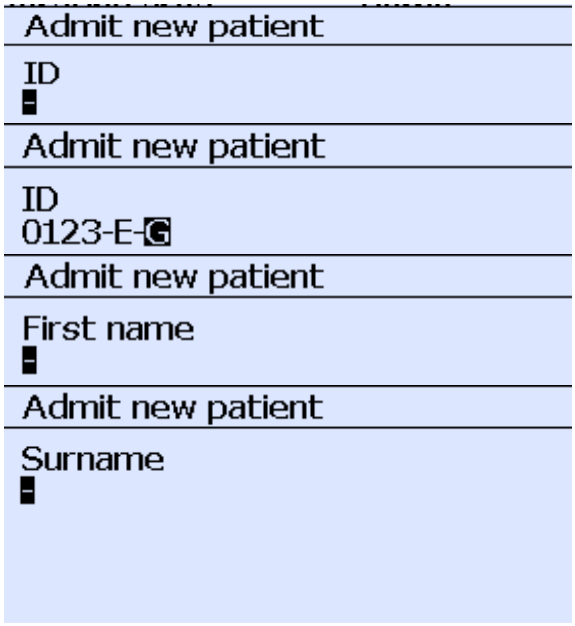


Fig. 57 System\ ID, First name, and Surname

Pressing the <Enter> key to confirm your entry in the SURNAME menu opens the submenu for setting the age group. Here too, press the <Enter> key to confirm your age group settings.

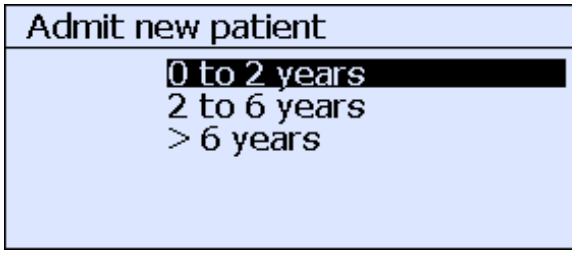


Fig. 58 System\ Age group

Use the ◁ key to highlight ACCEPT: YES and then press the <Enter> key, your settings for the new patient are stored.

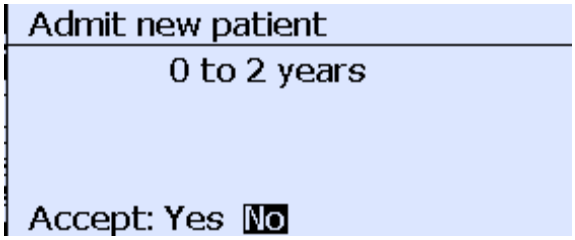


Fig. 59 Confirming the age group setting

The ADMIT NEW PATIENT function restores the factory settings.

VitaGuard® is delivered with alarm limits for patients in the 0 TO 2 YEARS age group.

The following settings vary with the age group:

- the minimum RESPIRATION RATE in the RESPIRATION menu
- the LOWER LIMIT and the UPPER LIMIT in the HEART RATE menu

The table lists the factory settings for each age group:

	0 to 2 years	2 to 6 years	>6 years
Min. respiration rate [/min]	10	5	4
Lower heart rate limit [/min]	80	60	55
Upper heart rate limit [/min]	220	150	120

All other settings are not specific to age groups.

The values set last are retained when VitaGuard® is switched off and when the supply network or batteries fail to provide power.

9.3.4 System\ Pre- and Post-alarm time

In the event of an alarm, data for the pre-alarm and post-alarm times set here are stored in addition to the duration of the alarm. These times can be set from 30 to 180 seconds in steps of ten seconds.

Also the menu item “System\ Interval recording” explained on page 91 records data for the duration of the pre-alarm and post-alarm times.

9.3.5 System\ Alarm mute time

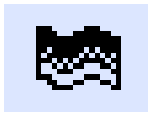
In order to allow caregivers to tend to a patient in peace during an alarm, the acoustic alarm signal can be temporarily deactivated with the <Esc> key. Set the Alarm mute time to 30, 60, 90, or 120 seconds as required. The acoustic alarm signal is automatically reactivated after this time.

9.3.6 System\ Date/ time

How to change these values is explained in the section “Changing multiple-component settings” on page 87. This is used to set the current date and the current time, e.g. for summer and winter times.

9.3.7 System\ Language

The menu option Language is marked with a flag symbol in the event that you do not understand the set language.



The submenu Language lets you choose between the languages supported by your monitor version.

9.3.8 System\ Analog input 1 + 2

You can activate and deactivate the two analog inputs separately. Both analog inputs have an input range from 0 to 2.5 V. An analog signal at input 1 (when activated) is scanned with 1 Hz and stored, a signal at input 2 is scanned with 32 Hz and stored.

9.3.9 System\ Interval recording

The doctor can use Interval recording for specific situations and can set an interval in steps of ten minutes after which monitored data are again stored. After each of these intervals, the monitor stores data for the Pre-alarm and Post-alarm times. The setting 0 min deactivates interval recording.

9.4 Data storage functions

The function Admit new Patient in the System menu overwrites all the currently stored data and restores the factory settings. If necessary, transfer the data beforehand to a PC.

The memory contents of VitaGuard® are also retained when the power adapter or batteries fail.

VitaGuard® features the following data storage functions:

- Event storage (automatic storage of Alarms and Silent Alarms or Manual storage)

- TREND storage (automatically for max 72 hours)
- INTERVAL storage (set in the SYSTEM menu)
- LONG TERM storage (automatically for max eight hours)
- PROTOCOL storage (automatic)

The VitaGuard® display lets you view stored EVENTS and stored TRENDS. LONG TERM and PROTOCOL storage can be evaluated on a PC only. The “Summary of stored signals and data” on page 97 presents the signals and sample rates for the respective memory. The currently utilized memory capacity is shown on the INFO display. The installed memory can store up to 200 events of two minutes each.

9.5 EVENT storage

Please bear in mind that you must wait for the POST-ALARM TIME to expire after an alarm has ended before the current alarm event can be completely stored.

The time of occurrence and the length of the stored data are stored for every alarm event. The section “Summary of stored EVENTS” on page 95 explains the symbols in the columns for each physiological parameter [⬆ ⬇ (⬆) (⬇) X P].

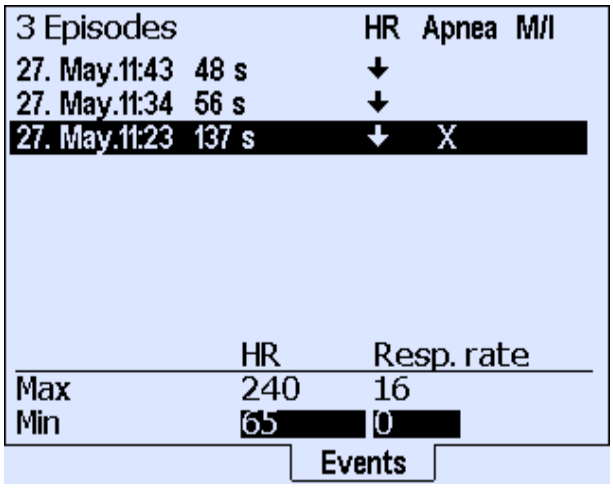


Fig. 60 List of the stored events

M/I marks the episodes that have been stored via MANUAL STORAGE or INTERVAL RECORDING set in the SYSTEM menu. The minimum and maximum values of the respective physiological parameters are seen at the bottom of the window.

Highlighting an alarm event with the direction keys △ and ▽ and pressing the <Enter> key opens a mask with initial detailed information on this event. Highlighting WAVEFORMS and pressing the <Enter> key displays the waveforms recorded with this event.

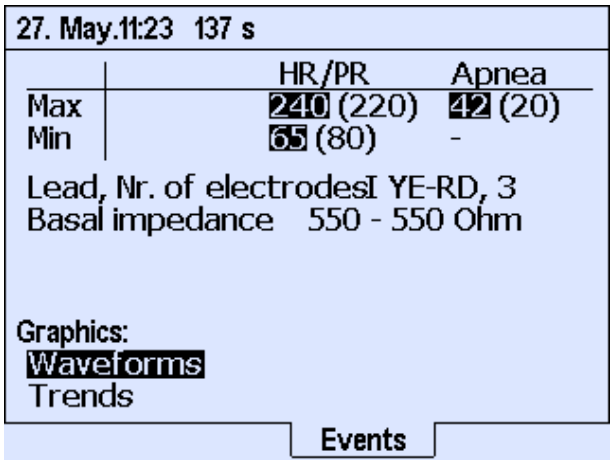


Fig. 61 Detailed information on a highlighted event

The black symbol between the displayed times for the start and end of the event marks the section of the stored event currently displayed. The two small vertical bars mark the start and end of the alarm event itself.

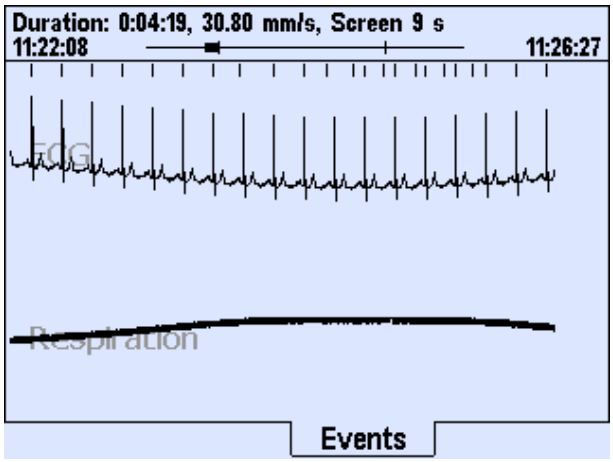


Fig. 62 Stored waveforms

Highlighting TRENDS and pressing the <Enter> key displays the TRENDS recorded with this alarm.

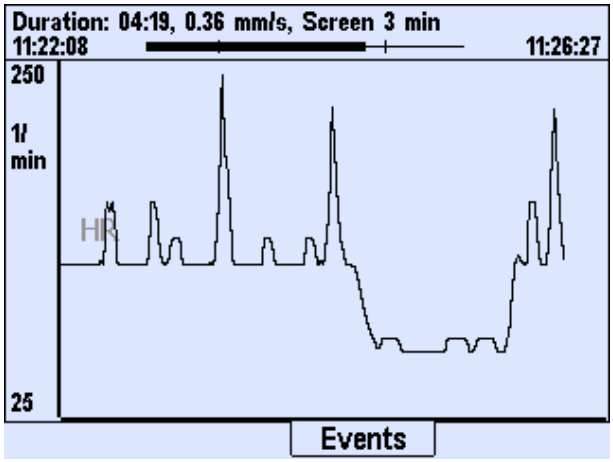


Fig. 63 Stored trends

9.5.1 Silent alarm limits

The monitor also lets you store signal sequences that are important for evaluating the selected alarm limits. To store these so-called “silent alarms”, activate Silent Alarm limits in the corresponding monitoring menu.

When measurements violate the Silent alarm limits, the current episode is stored without triggering an acoustic or visual alarm. For example, when the Silent lower limit is set higher than the Lower limit in the Heart rate menu, silent bradycardia alarms are stored.

9.5.2 Manual data storage or Transmit data

The △ or ▽ key takes you from View 1, 2, or 3 to the Manual data storage or Transmit data menu. In addition to the automatic storage of alarm events, you can also store current data manually. Manual data storage stores data for the set Pre- and Post-alarm times just like in an alarm situation.

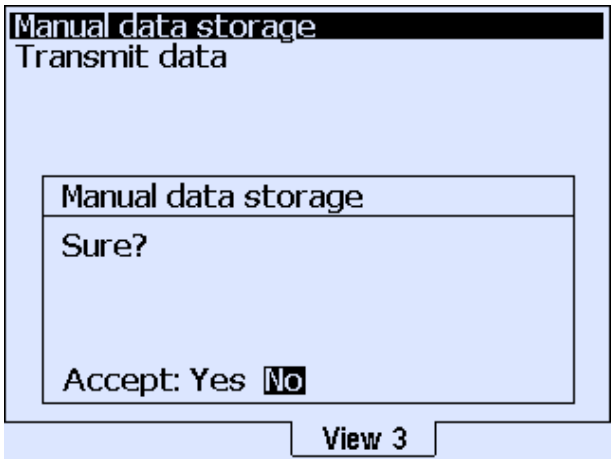


Fig. 64 View\ Manual data storage

The AUX socket is used to transmit data via a modem. The setting Since last transmission transfers only those new episodes stored since the last transfer, but no more than twenty.

The setting Last 20 episodes always transfers the last twenty episodes.

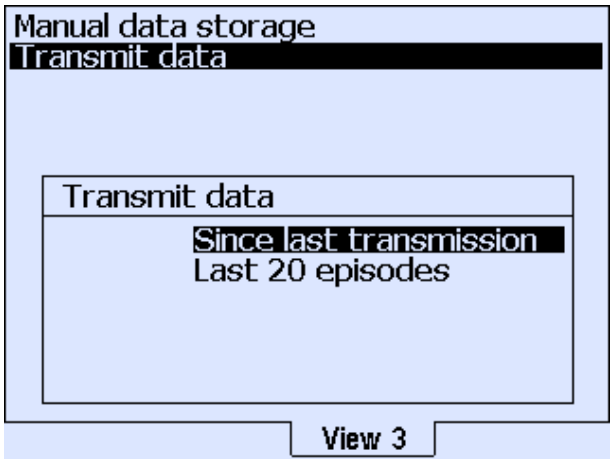
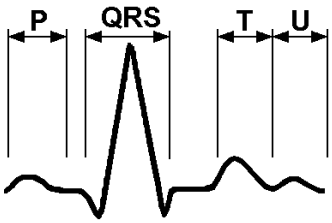


Fig. 65 View\ Transmit data

9.5.3 Summary of stored EVENTS

The symbols next to the name of each event appear on the EVENTS display in the columns for each physiological parameter following the time and duration of the event.

QRS ⬇ ..... ORS signal amplitude lower than the internal trigger threshold – an QRS alarm is reported when the ECG signal has not been detected, e.g. owing to badly positioned electrodes.



Bradycardia ⬇ ..... heart rate lower than the set LOWER LIMIT

Silent bradycardia **(⬇)** ... heart rate lower than the set silent LOWER LIMIT

Tachycardia ⬆ ..... heart rate higher than the set UPPER LIMIT

Silent tachycardia **(⬆)** ... heart rate higher than the set silent UPPER LIMIT

Heart rate drop ⬇ ..... when activated

Heart rate rise ⬆ ..... when activated

Manual **M** ..... manual storage (see "MANUAL DATA STORAGE or TRANSMIT DATA" on page 94)

Interval **I** ..... interval storage (see "SYSTEM\ INTERVAL RECORDING" on page 91)

Apnea **X** ..... one or more successive apneas

Silent apnea **(X)** ..... one or more short silent apnea phases, shorter than the set APNEA DELAY, but longer than the SILENT APNEA DELAY

Periodic respiration **P** ..... periodic respiration (see section 9.12)

9.6 TREND storage

When an episode is highlighted, pressing <Enter> once displays the details, and pressing it a second time the trends.

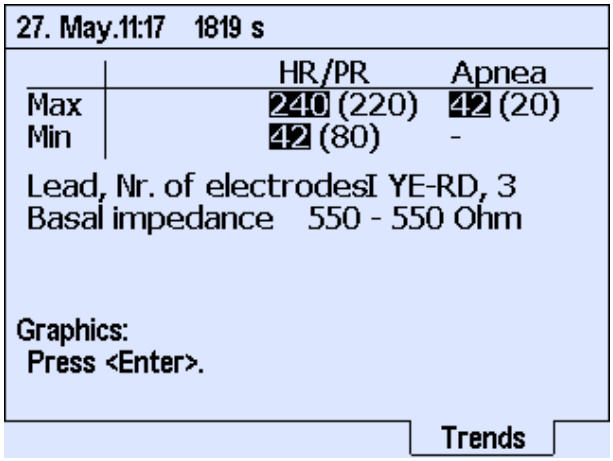


Fig. 66 List of the episodes stored in the trend memory

Over a max period of 72 hours the TREND memory stores all of the signals checked in the TREND column of the table on page 97.

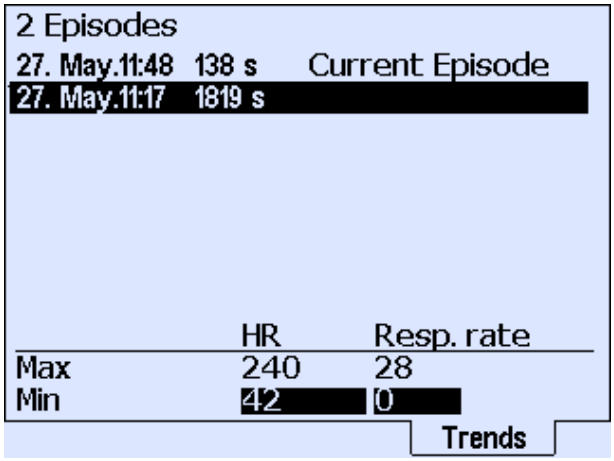


Fig. 67 Detailed information on a highlighted trend episode

9.7 LONG TERM storage over eight hours

Independent of alarm events, all signals are stored continuously for a maximum total time of eight hours for subsequent evaluation on a PC (full disclosure). After this period, the oldest data are overwritten.

9.8 PROTOCOL storage of operating and device data

The protocol memory registers e.g. when monitor settings are changed and when the device has been switched on and off. The following changes are stored in protocol memory:

- monitor ON/OFF
- apnea monitor ON/OFF
- admission of a new patient
- changes to SETTINGS PROTECTION

The following data are stored with every change:

- date and time of the change
- the current monitor settings

Protocol memory deletes the oldest data when more than 256 entries are stored.

9.9 Summary of stored signals and data

Data type	Sample rate [Hz]	ALARMS	LONG TERM	TREND
ECG waveform	256	✔	✔	
Current heart rate	1	✔	✔	✔
Average heart rate for trend deviation	1	✔	✔	✔
Average heart rate over 1 min	0.2	✔	✔	✔
Average heart rate over 1 h	0.2	✔	✔	✔
Average heart rate over 6 h	0.2	✔	✔	✔
Average heart rate over 12 h	0.2	✔	✔	✔
Respiration	128	✔	✔	
Respiration rate	1	✔	✔	✔
Basal impedance	1	✔	✔	✔
Status graph	0.1	✔	✔	✔
AUX1	1	✔	✔	✔
AUX2	32	✔	✔	

9.10 Settings in the HEART RATE menu (SETTINGS PROTECTION OFF)

For this setting, Settings protection must be set to Off as explained under “System\ Settings protection On, Limited, Off” on page 73.

The possible settings when SETTINGS PROTECTION is set to LIMITED are explained in the section “HEART RATE menu – alarm settings (Settings PROTECTION LIMITED)” on page 75.

Factory settings are shown in bold type.

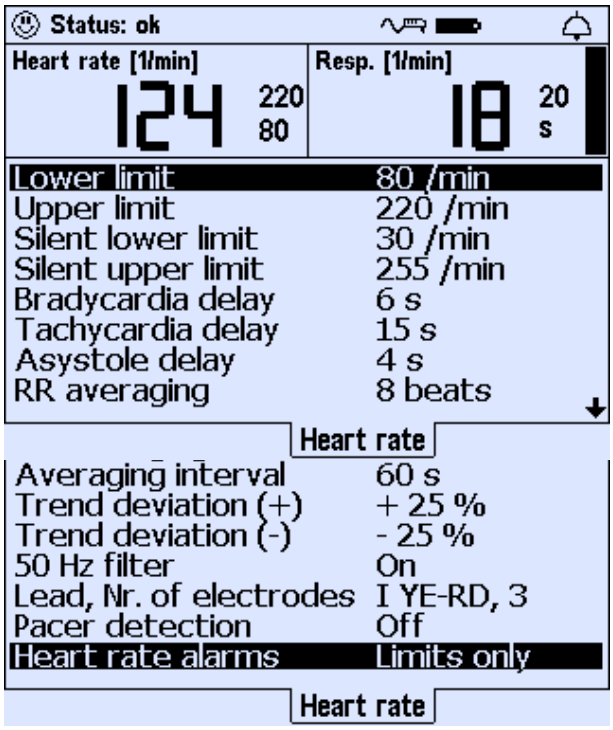


Fig. 68 Settings in the Heart rate menu

SILENT LOWER LIMIT (HEART) **30**, 35 ... 50 ... 175, 180/min
Lower limit for the heart rate; when the measured value falls below this limit for longer than the set BRADYCARDIA DELAY, a silent alarm is stored.

SILENT UPPER LIMIT (HEART) . 100, 105 ... **255**/min
See SILENT LOWER LIMIT.

BRADYCARDIA DELAY ..... 1, 2, 3, 4, 5, **6** ... 14, 15 seconds
Delay between when bradycardia is detected and the corresponding alarm is triggered.

TACHYCARDIA DELAY ..... 1, 2, 3, 4, 5 ... **15** ... 23, 24 seconds
See BRADYCARDIA DELAY, but for tachycardia.

ASYSTOLE DELAY	1, 2, 3, **4**, 5 ... 14, 15 seconds See BRADYCARDIA DELAY, but for asystole
RR AVERAGING	2. 4, 6, **8** ... 14, 16 beats Number of heartbeats used to calculate the heart rate – the displayed heart rate used to detect alarm conditions is calculated as an average value over the number of heartbeats set here. The greater the value chosen for RR averaging, the slower the system's reaction, particularly in the event of bradycardia, to report an alarm.
AVERAGING INTERVAL	10, 20 ... **60** ... 110, 120 seconds The average heart rate measured over the set interval yields the reference value for calculating TREND DEVIATION (+) and TREND DEVIATION (-).
TREND DEVIATION (+)	5, 10, 15, 20, **25**, 30, 35, 40, 45, 50% The current heart rate is compared with the average heart rate measured over the averaging interval and an alarm is reported when the set percentage deviation is exceeded. This alarm is reported only when HEART RATE ALARMS is set to LIMITS & TRENDS.
TREND DEVIATION (–)	See TREND DEVIATION (+), but the value falls below the set percentage deviation.
50 HZ FILTER	Setting the 50 Hz filter to **ON** suppresses interference signals, but also filters out parts of the ECG signal.
LEAD, NR. OF ELECTRODES	**I YE-RD, 3 (yellow–red, 3 electrodes)** II BK-RD, 3 (black–red, 3 electrodes)

III BK-YE, 3 (black–yellow, 3 electrodes)
I YE-RD, 2 (yellow–red, 2 electrodes)
Here you can determine which lead is used with two or three electrodes for detecting the ECG signal (explanations in the following).

PACER DETECTION ..... Activate this for pacemaker patients so that stimulating pacemaker pulses are not mistakenly processed as R waves; explanations can be found under “VitaGuard® and other medical devices” on page 81.

HEART RATE ALARMS ..... – When HEART RATE ALARMS is set to LIMITS ONLY, acoustic alarms are reported when the measured values violate the set alarm limits.
– When HEART RATE ALARMS is set to LIMITS & TRENDS, acoustic alarms are reported when the measured values violate the set alarm limits AND when there is a positive or negative deviation from the average heart rate measured over the set interval.

9.11 Changing the ECG lead for signal optimization

When the used lead frequently causes false heart rate alarms, another lead can be chosen. The default is lead I YE-RD, 3 (yellow–red, 3 electrodes). Signals can be optimized only when the patient is still or sleeping.

Bear in mind when optimizing the ECG lead that there must be no changes to the optimized positions of the red and yellow electrodes for detecting the respiration signal. When optimization becomes necessary, only the black electrode must be repositioned.

When replacing the electrodes, always choose the same electrode position and color.

To avoid too much of a strain on the patient's skin, you can also arrange the electrodes in a small circle around the optimal position.

By changing the ECG lead you can optimize separately the detection of respiration and heart signals for VitaGuard®.

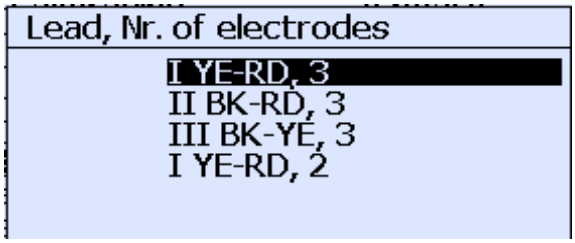


Fig. 69 Heart rate menu \ "Lead, Nr. of electrodes" submenu

- I YE-RD, 3 (yellow–red, 3 electrodes)

Both signals, the heart and the respiration signal, are measured between <yellow> and <red>.

- II BK-RD, 3 (black–red, 3 electrodes)

Like lead I, the respiration signal is measured between <red> and <yellow>, the heart signal on the other hand between <black> and <red>.

- III BK-YE, 3 (black–yellow, 3 electrodes)

Like lead I, the respiration signal is measured between <yellow> and <red>, the heart signal on the other hand between <black> and <yellow>.

- I YE-RD, 2 (yellow–red, 2 electrodes)

This lead is used when only two electrodes are to be attached.

Test the quality of the signal from the heart rate monitor with all leads.

When VIEW 1 displays the quality level GOOD for at least one of these leads, further optimization is not necessary.

The following explanations follow from the section “Determining the optimal electrode configuration” on page 53.

The electrode arrangement as depicted in Fig. 27 b (on page 54) is the standard Einthoven arrangement and normally yields good results for heart rate monitoring with the (yellow–red) lead.

1 Select the HEART RATE display, and note the amplitude of the displayed ECG signal. Press △ to open the menu, and note the setting for the ECG LEAD, e.g. "I YE-RD, 3”.

2 Select a different ECG LEAD, e.g. “II BK-RD, 3”. Press <Esc> to return to the HEART RATE display, and again note the displayed ECG amplitude.

3 Repeat the procedure for the last setting, i.e. “III BK-YE, 3”.

4 Select from all three leads the one that produces the greatest deflection. It is not important here whether this deflection is negative or positive.

Select the lead “I YE-RD, 3” when this is one of two leads that have produced approximately equal amplitudes.

When none of the leads produces a particularly large amplitude you should change the position of the black electrode and repeat the procedure. Carefully reapply the black electrode until you obtain the best signal amplitude.

When you reposition the electrodes, e.g. as depicted in Fig. 27 a), you must again check the ECG amplitude and, by repeating these steps, select the best lead for this new electrode configuration.

9.12 Settings in the Respiration menu (Settings protection Off)

For these settings, Settings protection must be set to Off as explained under "System\ Settings protection On, Limited, Off" on page 74. The possible settings when Settings protection is set to Limited are explained in the section "Respiration menu – alarm settings (Settings protection Limited)" on page 78.

Factory settings are shown in bold type.

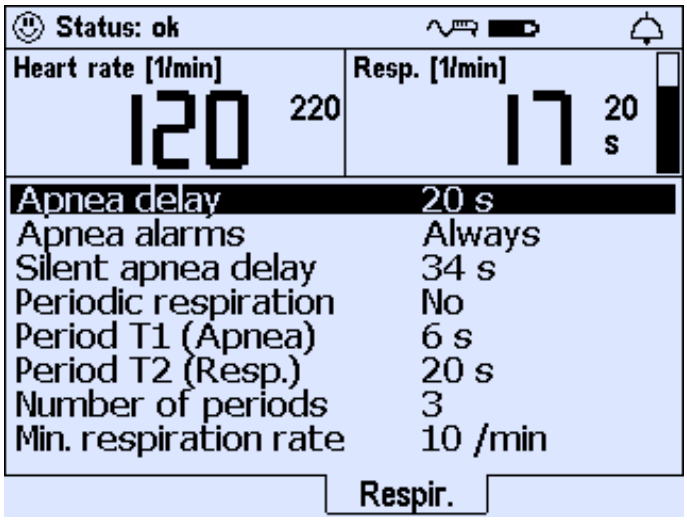


Fig. 70 Settings in the Respiration menu

Silent apnea delay ..... 8, 10 ... 22, **34** seconds
Same as Apnea delay, but a silent alarm is stored when exceeded.

Periodic respiration ..... Yes/**No**
This activates the detection of periodic respiration.

NOTE Activating the monitor for periodic respiration only operates if the age group 0–2 years has been previously selected.

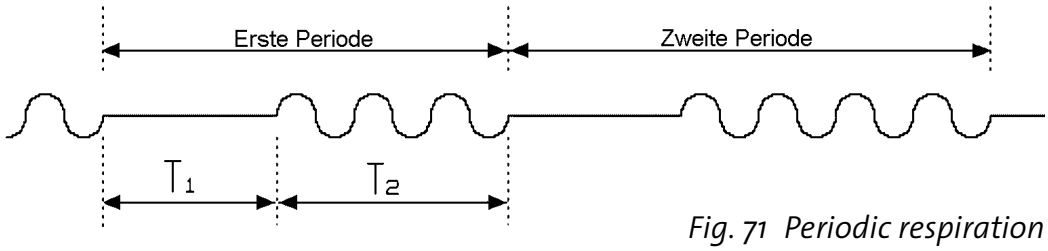


Fig. 71 Periodic respiration

Period T1 (Delay) ..... **6**, 8, 10 ... 18, 20 seconds
For the detection of periodic respiration apnea must be longer than T1, but shorter than the set Apnea delay.

PERIOD T2 (RESP.) ..... 4, 6, 8 ... **20** ... 28, 30 seconds
When resumed respiration lasts longer than T2, periodicity is no longer assumed.

NUMBER OF PERIODS ..... 2, **3** ... 5, 6 periods
When the set number of periodic cycles has been reached, the data are stored as a silent alarm.

MIN. RESPIRATION RATE ..... 4, 5, 6 ... 9, **10**/min
VitaGuard® discards signals with a lower rate of occurrence.

NOTE Changing the min respiration rate to 5/min has an effect only when the age group has been set to 0 TO 2 YEARS under SYSTEM\ ADMIT NEW PATIENT (see "SYSTEM\ ADMIT NEW PATIENT – restoring factory settings" on page 88). For the age group 2 TO 6 YEARS the min respiration rate is fixed at 5/min, for the age group > 6 YEARS at 4/min.

10 Algorithms and measuring principles

Knowledge of the following calculation bases is essential if VitaGuard® is to be properly configured.

10.1 Alarm condition and report delays

As prescribed in the standard IEC 60601-1-8 “General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems”, this section allows the doctor to become familiar with the set and inherent delays for the correct configuration of the alarm limits and monitoring parameters.

- The alarm *condition* delay is the time from the occurrence of a triggering event on the patient or in the monitor to the decision by the alarm system to confirm an alarm condition.
- The alarm *report* delay is the time between when an alarm condition is detected and when it is reported.
- The alarm *condition* delay and the alarm *report* delay are added to yield the ALARM SYSTEM delay.

The algorithms listed here are based on worst credible cases, i.e. the calculations always return the maximum possible delays.

10.1.1 Alarm condition delay for the heart rate

The current heart rate used for detecting alarm conditions is calculated as the average value over a set number of heartbeats (two to sixteen).

The higher the value selected for RR AVERAGING, the longer VitaGuard® needs before the displayed heart rate reflects the patient's actual heart rate. When, for example, a value N = 16 is chosen, the actual heart rate is not displayed until after sixteen heartbeats.

$$T_{AC(MAX)}\Big|_{HR} = 60\sum_{n=0}^{N-1}\frac{1}{HR_n}$$

whereby N = AVERAGING

The longest alarm condition delay for the heart rate therefore occurs when it is at its lowest. When, for example, the heart rate suddenly drops to thirty beats a minute, a beat is detected every two seconds. When RR AVERAGING is set to 16, a heart rate of thirty is not displayed until after thirty-two seconds.

10.1.2 Alarm condition delay for respiration

The impedance pneumography used to monitor apnea must rule out cardiac artifacts as the source of changes to measured impedance. When central apnea has occurred the applied algorithm detects cardiac artifacts after max four heartbeats.

The alarm condition delay for respiration depends in addition on the signal amplifier's recovery time. When in the worst case the amplifier is saturated owing to sudden, violent movements by the patient directly before the occurrence of apnea, the zero line is reached in six seconds. From then, again in the worst case, a period of four beats is needed before any cardiac artifacts can be detected.

$$T_{AC(MAX)}\Big|_{apnea} = 4\left(\frac{60}{HR}\right) + 6 \quad (6 = \text{amplifier's max recovery time in seconds})$$

10.1.3 Alarm report delays

The alarm report delays for bradycardia and tachycardia can be set within certain limits.

$TA_{(max)}$ for bradycardia: ..... set BRADYCARDIA DELAY + 2 s

$TA_{(max)}$ for tachycardia: ..... set TACHYCARDIA DELAY + 2 s

$TA_{(max)}$ for asystole: ..... set ASYSTOLE DELAY + 2 s

$TA_{(max)}$ for apnea: ..... 2 s

The purpose of these alarm report delays is to prevent alarms from being reported every time the alarm limits are violated for short times only.

In other words, the maximum alarm report delay corresponds to the maximum set delay. The monitor outputs measurements e.g. to the display every second. The technology's contribution to the total alarm report delay is specified as maximum two seconds overall.

10.2 Measuring principle for the heart rate monitor

Every heartbeat, i.e. contraction of the cardiac muscle, generates a myopotential that propagates through the body as an electric signal and that can be measured by two sensing electrodes attached to the body. The graphical depiction of the measured signal is called an electrocardiogram (ECG).

The amplitude and the polarity (positive or negative) of the measured signal depend on both the arrangement of the sensing electrodes and the individual location of the heart.

The signal is very weak (typically one millivolt), so it must be amplified before it can be used to calculate the heart rate.

For this purpose an instrumention amplifier is used in conjunction with filter circuitry. This amplifies the ECG signal and reduces all other unwanted secondary signals, e.g. movement-induced artifacts and electromagnetic interference.

Interference signals can be optimally suppressed, when a third, so-called reference electrode is used. Without this reference electrode, the ECG measuring circuitry must suppress interference signals solely with the aid of filters. When, however, interference signals exceed a certain limit, suppression is no longer possible and the ECG signal can no longer be measured; false alarms are the consequence. The use of

a reference electrode is the most common method for effecting an essentially greater suppression of interference.

The adhesive quality and the composition of the gel applied to the electrodes have an additional important effect on ECG measurements. The best results are obtained when the electrodes adhere well. Electrodes that have dried out or adhere badly are unsuitable.

Irrespectively of all interference signals, the heart rate can be measured only when the amplitude of the measured ECG signal itself is large enough to be detected by the monitor. Normally the amplitude of the ECG signal detected on the body surface cannot be influenced and varies from person to person.

The monitor measures the potential difference between the two sensing electrodes. Depending on where the electrodes are attached, the measured signal is strong, weak, positive, or negative. It is even possible that a signal cannot be seen at all. This is the case when the electrodes are inadvertently placed on the same potential line. The propagating signal from a heartbeat can be pictured as contour lines around a hill on a map. When two persons are standing on the same line, the difference in height between these persons is zero. Accordingly, no ECG signal can be measured when the sensing electrodes are placed on such a line on the body surface. To prevent too weak ECG signals from triggering false alarms, it is therefore important that the optimal electrode positions are determined before the start of monitoring.

10.3 Measuring principle for the apnea monitor

Unlike the heartbeat, respiration is not accompanied by its own electric signal. A different principle must therefore be adopted for measuring respiration. The most common method is the so-called impedance pneumography. Fluctuations in impedance are caused by both respiratory movements of the thorax and other movements. For this reason, an apnea monitor can function correctly only when the patient is lying still. Here too, the measured signals are very weak and must be amplified. To prevent false alarms wherever possible, it is

very important that the optimal electrode positions are determined before the start of monitoring.

The essential advantage of the described method is that the same electrodes can be used for monitoring the heart rate and respiration.

11 Evaluating stored data on a PC

getemed AG has developed the Windows®-based software VitaWin® for evaluating the recorded monitoring data. This software is provided only to doctors and authorized dealers who are or supply VitaGuard® users.

The stored data can be downloaded through the USB (universal serial bus) port to a PC where they can be stored, viewed, and evaluated.

VitaWin® presents each alarm's context based on the signals RESPIRATION, RESPIRATION RATE, BASAL IMPEDANCE, ECG and HEART RATE.

VitaWin® also provides functions for drawing up reports and assessing the patient's monitored data.

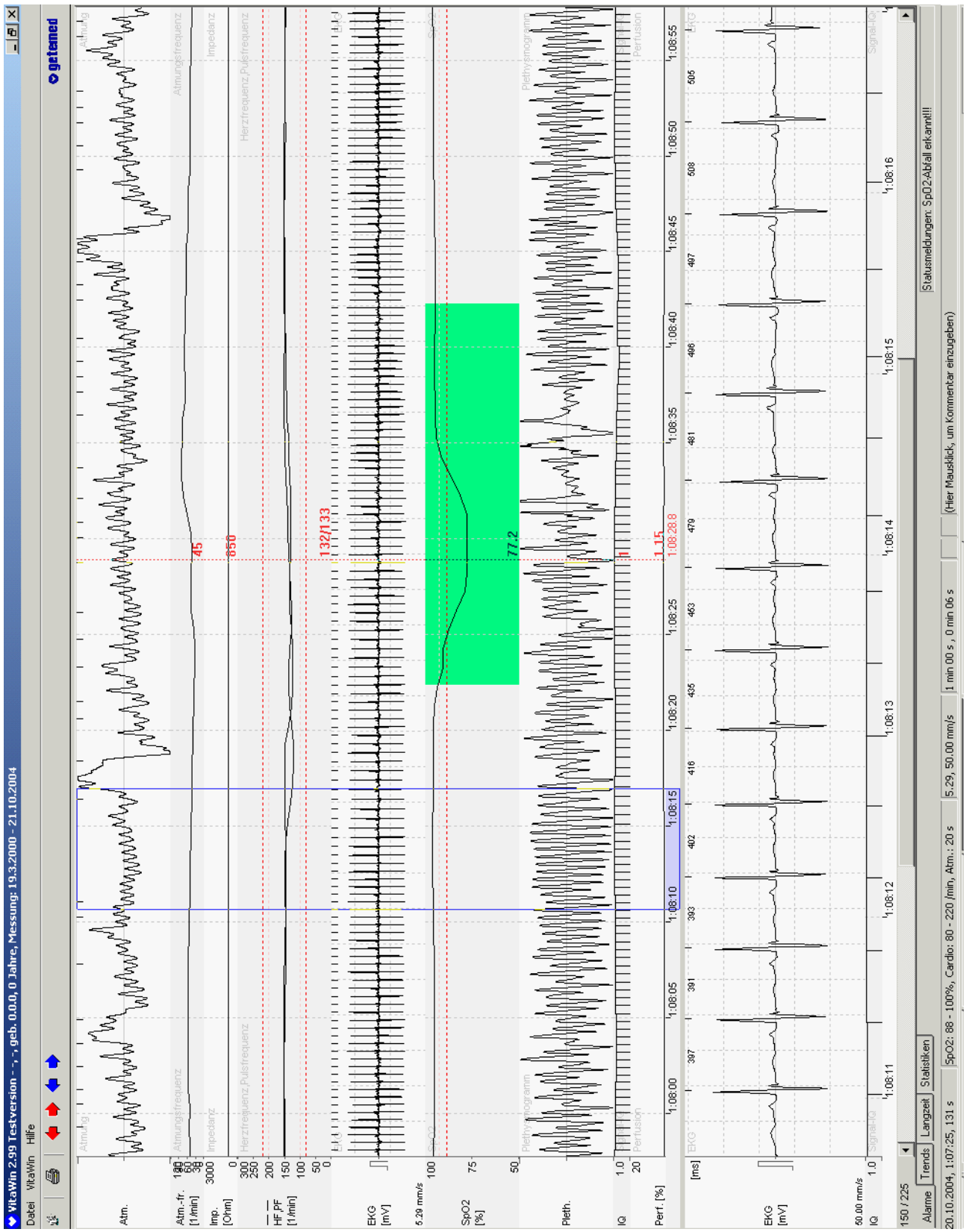


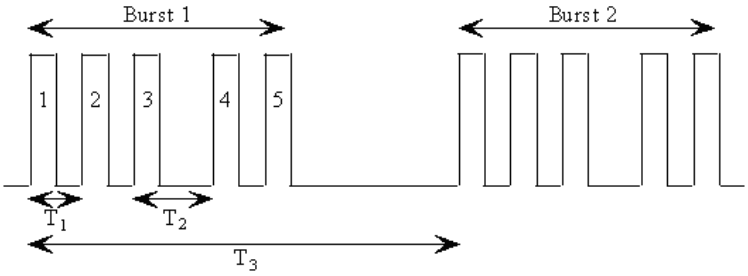
Fig. 72 VitaWin®\ register "Events in graph form"

12 Specifications

12.1 General

Weight	approx. 650 g with non-rechargeable batteries approx. 700 g with rechargeable block battery
Dimensions	13.5 x 20.3 x 4.5 cm
Non-rechargeable batteries	4 x 1.5 V (type LR6, AA), alkaline
Chargeable block battery	NiMH/4.8 V/2000 mAh
Charging time	6 hours
Battery life	e.g. VARTA UNIVERSAL ALKALINE: minimum 2 days
Keys	6 membrane keys
Battery change	displayed message
Depleted battery	acoustic alarm
Power consumption	< 10 W
Power adapter	NA3000-2 power adapter Manufacturer: FRIWO Gerätebau GmbH Type: FW 7555MM / 09 Output: 9 V, 1500 mA, DC Input: 100–240 V, 50–60 Hz, 400 mA, AC Ingress of protection: IP 40

Characteristics of acoustic alarm signals ..... acoustic signals for higher-priority alarms consist of two acoustic sequences of five tones each:



Pulse duration	-	155 ms ± 5 ms
Rise and fall time	-	17 ms ± 3 ms
Time between start of pulse 1 and start of pulse 2	T_1	215 ms ± 20 ms
Time between start of pulse 2 and start of pulse 3	T_1	215 ms ± 20 ms
Time between start of pulse 3 and start of pulse 4	T_2	440 ms ± 20 ms
Time between start of pulse 4 and start of pulse 5	T_1	215 ms ± 20 ms
Time between start of burst 1 and start of burst 2	T_3	2 s ± 0.1 s
Repeat time for the whole sequence	-	10 s ± 0.2 s

acoustic signals for medium-priority alarms consist of three-pulse bursts:

Pulse duration	185 ms ± 5 ms
Rise and fall time	17 ms ± 3 ms
Time between start of pulse 1 and start of pulse 2	375 ms ± 20 ms
Time between start of pulse 2 and start of pulse 3	375 ms ± 20 ms
Repeat time for the whole sequence	5.2 s ± 0.2 s

Characteristics of system monitoring signals	pulsating tone of 4 kHz and 1 Hz pulse rate from the sound aperture between the sockets
Displays	LEDs and LCD graphic display with 240 x 360 dots
Display refresh rate	1 Hz
Expected service life (as per DIN EN ISO 18778)	min seven years
Inspection and servicing intervals	getemed AG prescribes safety checks, function checks, and servicing every eighteen months. The next appointment is specified on a label in the battery compartment.

12.2 Heart rate monitor

Heart rate range	20–270/min
Accuracy	±1% for heartbeats of similar morphology (averaged over 4 to 16 beats)
Sensitivity	0.2 mV ($\sin^2$ signal with 40 ms width)
Input impedance	> 10 MΩ at 10 Hz

12.3 Apnea monitor

Max. respiration rate	120 breaths/min
Min. respiration rate	4, 5, or 10 breaths/min, depending on AGE GROUP setting

Alarm quit	2 breaths within 6 seconds
Sensitivity of respiration amplifier	approx. 0.2 Ω/1000 Ω
Measuring method	impedance pneumography
Measuring current frequency	38 kHz
Measuring current	< 100 µA

12.4 Intervals for calculating average values in the INFO mask

Minute value HR	1 s
Hour value HR	30 s
Six-hour value HR	300 s
Twelve-hour value HR	300 s

12.5 Memory

Storage medium	64 MB compact flash memory card (memory extendable on request)
Nr. of episodes	max 200 episodes of two minutes each
Trend	max 72 hours
Long term (full disclosure)	max 8 hours

12.6 Ports

USB	mini USB port

AUX	– modem port (RS232) – socket for a nurse call system – socket for an external alarm unit – socket for two analog inputs from 0 to 2.5 V at 1 or 32 Hz

12.7 Miscellaneous

Calibrating time after activation	< 60 s
MPG device class	IIb
Device protection class	II as per DIN EN 60601-1
Application part	type CF
Ingress protection	IP 21
Operating temperature	5–40 °C
Operating humidity	5–95%, non-condensing
Ambient pressure, height above sea level	1060–500 mbar, -304 to +5486 m
*Storage and transport conditions	–40 to +70 °C; humidity 15–95%, non-condensing
EMC classification	CISPR 11, class B

***Observe the information on the electrodes' packaging for the storage temperature of electrodes.**

12.8 Selection of applied standards

IEC 601-1	Medical electrical equipment – Part 1: General requirements for safety, incl. A 13
IEC 60601-1-1	Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-4	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems
IEC 62A/422/CDV:2003 (prEN 60601-1-6:2003)	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability
IEC 60601-1-8	Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 601-2-27	Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

DIN EN 60601-2-49	Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunctional patient monitoring equipment
prEN ISO 18778	Infant Monitors – Particular requirements

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